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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, March 13, 2012
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0562; Directorate Identifier 2009–NE–29–AD; Amendment 39–16969; AD 2012–04–13]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc (RR) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for all RR model RB211–524G2–T–19, –524G3–T–19, –524H–T–36, and –524H2–T–19; and RB211–Trent 553–61, 553A2–61, 556–61, 556A2–61, 556B–61 556B2–61, 560–61, 560A2–61; RB211–Trent 768–60, 772–60, 772B–60; and RB211–Trent 875–17, 877–17, 884–17, 884B–17, 892–17, 892B–17, and 895–17 turbofan engines that have a high-pressure (HP) compressor stage 1 to 4 rotor disc with a part number (P/N) listed in Table 1 of the AD. That AD currently requires repetitive inspections of the axial dovetail slots, and follow-on corrective action depending on findings. Since we issued that AD, we determined that the definition of shop visit is too restrictive in the existing AD. This continues to require those repetitive inspections and follow-on corrective actions. This new AD changes the definition of a shop visit to be less restrictive. This AD was prompted by our determination that the definition of ''shop visit'' in the existing AD is too restrictive, in that it would require operators to inspect more often than required to ensure safety. We are issuing this AD to detect cracks in the HP compressor stage 1 and 2 disc posts, which could result in failure of the disc post and HP compressor blades, release of uncontained engine debris, and damage to the airplane.

DATES: This AD is effective April 11, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of April 11, 2012.

ADDRESSES: For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–245418 or email from *http://www.rolls-royce.com/contact/civil_team.jsp,* or download the publication from *https://www.aeromanager.com.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7143; fax: 781–238–7199; email: *alan.strom@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2011–09–07, Amendment 39–16669 (76 FR 24793, May 3, 2011). That AD applies to the specified products. The NPRM published in the **Federal Register** on October 20, 2011 (76 FR 65136). That NPRM proposed to continue to require initial and repetitive fluorescent penetrant inspections of the HP compressor stage 1 to 4 rotor discs at the first shop visit after accumulating 1,000 cycles-since-new on the stage 1 to 4 rotor discs or at the next shop visit after the effective date of that AD, which ever occurs later. That NPRM also proposed to continue to require repetitive inspections at every shop visit. That NPRM also proposed to change the definition of a shop visit to be less restrictive.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and the FAA's response to each comment.

Support for the NPRM

Two commenters, the Boeing Company and American Airlines, support the intent of the NPRM (76 FR 65136, October 20, 2011).

Request To Change From a Supersedure to a Revision

One commenter, American Airlines, requested that we change the proposed AD (76 FR 65136, October 20, 2011) from being an AD supersedure to being an AD revision of the existing AD 2011–09–07 (76 FR 24793, May 3, 2011), or, have Rolls-Royce plc revise Alert Service Bulletin (ASB) No. RB.211–72–AF964 to remove the reference to AD 2011–09–07, so that we can reference that latest ASB revision in the AD. The commenter stated that the ASB revision should be issued before the AD is issued, and referenced in the AD, to avoid the burden of needing global Alternative Methods of Compliances written.

We do not agree. The reference to the previous AD (76 FR 24793, May 3, 2011) in ASB No. RB.211–72–AF964 is not the section of the ASB incorporated by reference by this AD. We can not delay publishing an AD to wait for an administrative change to a service bulletin. Administrative updates to service bulletins are made for a variety of reasons. These revisions are easily handled by the alternative method of compliance process described in paragraph (i) of this AD. We did not change the AD.

Conclusion

We reviewed the relevant data, considered the comments received, and

determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

Based on the service information, we estimate that this AD will affect about 371 products of U.S. registry. We also estimate that it will take about 20 work-hours per product to comply with this AD. The average labor rate is $85 per work-hour. No parts will be required per product. Based on these figures, we estimate the cost of the AD on U.S. operators to be $630,700.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2011–09–07, Amendment 39–16669 (76 FR 24793, May 3, 2011), and adding the following new AD:

2012–04–13 Rolls-Royce plc: Amendment 39–16969; Docket No. FAA–2010–0562; Directorate Identifier 2009–NE–29–AD.

(a) Effective Date

This airworthiness directive (AD) is effective April 11, 2012.

(b) Affected ADs

This AD supersedes AD 2011–09–07, Amendment 39–16669 (76 FR 24793, May 3, 2011).

(c) Applicability

This AD applies to Rolls-Royce plc (RR) model RB211–524G2–T–19, –524G3–T–19, –524H–T–36, and –524H2–T–19; and RB211–Trent 553–61, 553A2–61, 556–61, 556A2–61, 556B–61 556B2–61, 560–61, 560A2–61; RB211–Trent 768–60, 772–60, 772B–60; and RB211–Trent 875–17, 877–17, 884–17, 884B–17, 892–17, 892B–17, and 895–17 turbofan engines that have a high-pressure (HP) compressor stage 1 to 4 rotor disc with a part number (P/N) listed in Table 1 of this AD.

TABLE 1—AFFECTED HP COMPRESSOR STAGE 1 TO 4 ROTOR DISC P/NS BY ENGINE MODEL

Engine model	HP compressor stage 1 to 4 rotor disc P/N
(1) RB211–524G2–T–19, –524G3–T–19, –524H–T–36, and –524H2–T–19.	FW20195, FK25502, or FW23711.
(2) RB211 Trent 553–61, 553A2–61, 556–61, 556A2–61, 556B–61, 556B2–61, 560–61, and 560A2–61.	FK30524.
(3) RB211 Trent 768–60, 772–60, and 772B–60	FK22745, FK24031, FK26185, FK23313, FK25502, FK32129, FW20195, FW20196, FW20197, FW20638, or FW23711.
(4) RB211 Trent 875–17, 877–17, 884–17, 884B–17, 892–17, 892B–17, and 895–17.	FK24009, FK26167, FK32580, FW11590, or FW61622.

(d) Unsafe Condition

This AD was prompted by our determination that the definition of ''shop visit'' in the existing AD is too restrictive, in that it would require operators to inspect more often than required to ensure safety. We are issuing this AD to detect cracks in the HP compressor stage 1 and 2 disc posts, which could result in failure of the disc post and HP compressor blades, release of uncontained engine debris, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(f) Cleaning and Inspection

(1) Clean and perform a fluorescent penetrant inspection of the HP compressor stage 1 to 4 rotor discs at the first shop visit after accumulating 1,000 cycles since new on the stage 1 to 4 rotor discs or at the next shop visit after the effective date of this AD, which ever occurs later.

(2) Use paragraph 3.A through 3.E.(11) of the Accomplishment Instructions of Rolls-Royce Alert Service Bulletin (ASB) No. RB.211–72–AF964, Revision 2, dated June 8, 2011, to do the inspections.

(3) Thereafter at every engine shop visit, perform the inspection specified by paragraph (f) of this AD.

(g) Definition

For the purpose of this AD, an ''engine shop visit'' is whenever all compressor blades are removed from the HP compressor drum.

(h) Credit for Previous Action

A cleaning and inspection performed before the effective date of this AD using Rolls-Royce ASB No. RB.211–72–AF964, Revision 1, dated June 6, 2008, or Revision 2, dated June 8, 2011, satisfies a cleaning and inspection cycle required by this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA may approve AMOCs for this AD. Use

the procedures found in 14 CFR 39.19 to make your request.

(j) Related Information

(1) For more information about this AD, contact Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7143; fax: 781–238–7199; email: *alan.strom@faa.gov.*

(2) See European Aviation Safety Agency Airworthiness Directive 2009–0073R1, dated April 8, 2009, for related information.

(k) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51 of the following service information on the date specified:

(i) Rolls-Royce Alert Service Bulletin No. RB.211–72–AF964, Revision 2, dated June 8, 2011 approved for IBR April 11, 2012.

(ii) Rolls-Royce ASB No. RB.211–72–AF964, Revision 1, dated June 6, 2008 approved for IBR June 7, 2011 (76 FR 24793, May 3, 2011).

(2) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–245418 or email from *http://www.rolls-royce.com/contact/civil_team.jsp,* or download the publication from *https://www.aeromanager.com.*

(3) You may review copies of the service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr_locations.html.*

Issued in Burlington, Massachusetts, on February 23, 2012.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–5370 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0959; Directorate Identifier 2011–NE–25–AD; Amendment 39–16970; AD 2012–04–14]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for RB211–Trent 800 series turbofan engines. This AD requires inspecting the front combustion liner head section for cracking, and if found cracked, removing the front combustion liner head section from service at the next shop visit. This AD was prompted by mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. Specifically, routine inspections revealed cracking on the head sections of two RB211–Trent 800 front combustion liners. We are issuing this AD to prevent uncontained engine failure and damage to the airplane.

DATES: This AD becomes effective April 11, 2012. The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 11, 2012.

ADDRESSES: The Docket Operations office is located at Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

FOR FURTHER INFORMATION CONTACT: Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *alan.strom@faa.gov;* phone: 781–238–7143; fax: 781–238–7199.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on November 25, 2011 (76 FR 72650). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Routine inspections have revealed cracking on the head sections of two Trent 800 front combustion liners.

This condition, if not detected and corrected, could lead to hot gas breakout with subsequent downstream component release potentially leading to uncontained high energy debris, possibly resulting in damage to the aeroplane or injury to persons on the ground.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received.

Request To Reference the Latest Service Information

American Airlines, The Boeing Company, and Rolls-Royce plc, requested that we reference the latest service information, which is Alert Service Bulletin (ASB) No. RB.211–72–AG456, Revision 1, dated November 4, 2011.

We agree. We changed the AD to reference Revision 1 of the ASB.

Request To Add Previous Credit Paragraph

American Airlines, The Boeing Company, and Rolls-Royce plc, requested that we add a Previous Credit paragraph to list the original ASB to give credit to operators who have performed the initial and repetitive inspections before the effective date of the AD.

We agree. We added Credit for Previous Action paragraph (i) to the AD.

Request To Borescope-Inspect the 04 Module When Removed

Rolls-Royce plc requested that we add wording to the AD that states that the 04 module may be borescope-inspected when it is removed from the engine but is not being stripped. This would give the operator the opportunity to restart the 2,000-cycle on-wing life before the next inspection, or if cracked, would give the operator the opportunity to replace the front combustion liner head section.

We agree. We changed the AD to allow as an alternate procedure, an in-shop borescope inspection.

Request To Eliminate Unnecessary Borescope Inspection

Rolls-Royce plc pointed out that the proposed AD requires the front combustion liner head section to be borescope inspected even if it is being stripped. Visual and fluorescent penetrant inspections would be done as part of the maintenance manual activities after stripping, and the borescope inspection would be unnecessary.

We agree. We changed the AD to eliminate the unnecessary borescope inspection.

Request To Clarify AD Meaning

American Airlines and The Boeing Company requested that we change paragraphs (f)(2) and (g)(1)(i) to state that if you find cracking, repetitively inspect the front combustion liner as specified in Table 1 and remove it from service as specified in Table 1 or at the next shop visit, whichever occurs first. The commenters claim that this change would clarify the meaning of the AD.

We do not agree. Any engine found to have cracks during the initial inspection in paragraph (f)(1) or a repetitive inspection in paragraph (g)(1) must have its front combustor liner head section removed from service at the next shop visit. Table 1 allows for further flight with mitigating actions until the next shop visit. We did not change the AD.

Request To Identify the Repetitive Inspections Paragraph

The Boeing Company requested that we identify the repetitive inspections paragraph, as paragraph (g).

We do not agree. The paragraph is already identified as paragraph (g). We did not change the AD.

Request To Remove Erroneous Reference

American Airlines requested that in paragraph (g)(2), we not reference paragraph (f)(2) as being a step that would find cracks, because it does not.

We agree. We removed that reference in the AD.

Request To Revise Shop Visit Definition and To Inspect During All Shop Visits

American Airlines requested that we revise the definition of shop visit to include all engine shop visits, and revise paragraph (g)(2) of the proposed AD such that paragraph 3.B.(1) or 3.B.(2) of the ASB can be used to do the inspections. The commenter stated that the proposed AD shop visit definition limits the number of shop visits where an inspection is required. Further, paragraph (g)(2) of the proposed AD is inconsistent with the definition of shop visit in the ASB because the ASB has instructions for borescope inspection when the front combustor liner head section is not exposed.

We partially agree. We agree with revising paragraph (g)(2) (now paragraph (g)(3) in the AD) and paragraph (h), because Revision 1 of the ASB is worded differently from the original ASB, and Revision 1 of the ASB added an alternate borescope inspection that can be performed without disassembling the 04 module.

We do not agree with requiring the inspection during all shop visits because the mitigating actions in Table 1 of the AD are sufficient to ensure safe operation pending a shop visit in accordance with the definition of shop visit in the AD. We changed paragraph (g)(2) (now paragraph (g)(3)) from:

''For engines not found to have cracks in the front combustion liner head section in accordance with paragraphs (f)(1), (f)(2), or (g)(1) of this AD, at every shop visit after the effective date of this AD, inspect the front combustion liner head section for cracking. Use paragraph B.(2), except B.(2)(a)(i), of the In-shop Accomplishment Instructions of RR ASB No. RB.211–72–AG456, dated September 9, 2010, to do the inspections,'' to:

''For engines not found to have cracks in the front combustion liner head section in accordance with paragraphs (f)(1) or (g)(1) of this AD, at every shop visit after the effective date of this AD:

(i) Fluorescent-penetrant inspect the front combustion liner head section for cracking; or

(ii) Borescope-inspect the front combustion liner head section for cracking. Use paragraph 3.B.(1)(b) except paragraph 3.B.(1)(b)(i), or use paragraphs 3.B.(2)(b) through 3.B.(2)(d), of the In-shop Accomplishment Instructions of RR ASB No. RB.211–72–AG456, Revision 1, dated November 4, 2011.

(iii) If any cracks are found, reject the front combustion liner.''

We also changed paragraph (h) from:

''For the purpose of this AD, the term shop visit means the induction of an engine into the shop for maintenance where the front combustion liner is exposed or when the engine has been removed from service as a result of paragraph (f)(2) or (g)(1)(i) of this AD,'' to:

''For the purpose of this AD, the term shop visit means the induction of an engine into the shop for maintenance where the front combustion liner is exposed, or when the 04 module has been removed from the engine or when the engine has been removed from service as a result of paragraph (f)(2) or (g)(2) of this AD.''

Request To Change Action Wording in Table 1

The Boeing Company requested that we change the action wording in Table 1 of the proposed AD from ''Replace the engine before next flight'' to ''Remove the engine immediately.'' The commenter stated that this would make the AD consistent with the ASB and prevent failures on the ground.

We do not agree. Engine running on the ground is not a flight safety issue. We note, however, that the NPRM (76 FR 72650, November 25, 2011) used both ''remove the engine'' and ''replace the engine'' in Table 1. We changed Table 1 in the AD to use the phrase, ''remove the engine'' in each case.

Need To Show All Acceptable Means of Completing the On-Wing Inspection

Since we issued the NPRM (76 FR 72650, November 25, 2011), we determined that to be consistent with Revision 1 of the ASB, we need to show all acceptable means of completing the on-wing inspection. We changed paragraphs (f)(1) and (g)(1) of the proposed AD from:

''Within 1,000 flight cycles (FCs) after the effective date of this AD, inspect the front combustion liner head section for cracking. Use paragraph 3.A, except for 3.A.(1)(a)(i), of the On-Wing Accomplishment Instructions of RR ASB No. RB.211–72–AG456, dated September 9, 2010, to do your inspections'' to:

''Within 1,000 flight cycles (FCs) after the effective date of this AD, inspect the front combustion liner head section for cracking. Use paragraph 3.A.(1), except for 3.A.(1)(a)(i), or paragraphs 3.A.(2)(b) through 3.A.(2)(d) of the On-Wing Accomplishment Instructions of RR ASB No. RB.211–72–AG456, Revision 1, dated November 4, 2011, to do your inspections.''

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Costs of Compliance

We estimate that this AD will affect about 125 products of U.S. registry. We also estimate that it will take about 10 work-hours per engine to inspect and 10 additional work-hours for those combustion liners that require replacement. The average labor rate is $85 per work-hour. Required parts will cost about $525,000 per engine. We expect that four front combustion liners will require replacement. Based on these figures, we estimate the cost of the AD on U.S. operators to be $2,209,650.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (phone: 800–647–5527) is provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2012–04–14 Rolls-Royce plc: Amendment 39–16970; Docket No. FAA–2011–0959; Directorate Identifier 2011–NE–25–AD.

(a) Effective Date

This AD becomes effective April 11, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211–Trent 800 turbofan engines, all models, all serial numbers.

(d) Reason

(1) This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Routine inspections have revealed cracking on the head sections of two Trent 800 front combustion liners.

This condition, if not detected and corrected, could lead to hot gas breakout with subsequent downstream component release potentially leading to uncontained high energy debris, possibly resulting in damage to the aeroplane or injury to persons on the ground.

(2) We are issuing this AD to prevent uncontained engine failure and damage to the airplane.

(e) Actions and Compliance

Unless already done, do the following actions.

(f) Initial Inspection

(1) Within 1,000 flight cycles (FCs) after the effective date of this AD, inspect the front combustion liner head section for cracking. Use paragraph 3.A.(1), except for 3.A.(1)(a)(i), or paragraphs 3.A.(2)(b) through 3.A.(2)(d) of the On-Wing Accomplishment Instructions of RR Alert Service Bulletin (ASB) No. RB.211–72–AG456, Revision 1, dated November 4, 2011, to do your inspections.

(2) If you find cracking, remove the front combustion liner head section from service at the next shop visit. Until the next shop visit, take the corrective actions listed in Table 1 of this AD, as applicable.

TABLE 1—INSPECTION FINDINGS AND FOLLOW-ON ACTIONS

Inspection findings	Action(s) and compliance time(s)
(i) Cumulative crack length up to 150 mm (up to 2 heatshields)	Reduce the inspection intervals to 250 FCs.
(ii) Cumulative crack length 150 mm to 300 mm (up to 4 heatshields)	Reduce the inspection intervals to 100 FCs.
(iii) Cumulative crack length 300 mm to 450 mm (up to 6 heatshields)	Remove the engine within 50 FCs.
(iv) Cumulative crack length 450 mm to 900 mm (up to 12 heatshields)	Remove the engine within 5 FCs.
(v) Cumulative crack length greater than 900 mm (more than 12 heatshields)	Remove the engine before next flight.

(g) Repetitive Inspections

(1) Within 1,000 FCs after the effective date of this AD, inspect the front combustion liner head section for cracking. Use paragraph 3.A.(1), except for 3.A.(1)(a)(i), or paragraphs 3.A.(2)(b) through 3.A.(2)(d) of the On-Wing Accomplishment Instructions of RR ASB No. RB.211–72–AG456, Revision 1, dated November 4, 2011, to do your inspections.

(2) If you find cracking, remove the front combustion liner head section at the next shop visit. Until the next shop visit, take the corrective actions as detailed in Table 1 of this AD, as applicable.

(3) For engines not found to have cracks in the front combustion liner head section in accordance with paragraphs (f)(1) or (g)(1) of this AD, at every shop visit after the effective date of this AD:

(i) Fluorescent-penetrant inspect the front combustion liner head section for cracking; or

(ii) Borescope-inspect the front combustion liner head section for cracking. Use paragraph 3.B.(1)(b) except paragraph 3.B.(1)(b)(i), or use paragraphs 3.B.(2)(b) through 3.B.(2)(d), of the In-shop Accomplishment Instructions of RR ASB No. RB.211–72–AG456, Revision 1, dated November 4, 2011.

(iii) If any cracks are found, reject the front combustion liner.

(4) Accomplishment of a shop visit inspection as required by paragraph (g)(3) of this AD may substitute for the accomplishment of an on-wing inspection as

required by paragraph (f)(1) or (g)(1) of this AD.

(h) Definition of Shop Visit

For the purpose of this AD, the term shop visit means the induction of an engine into the shop for maintenance where the front combustion liner is exposed, or when the 04 module has been removed from the engine, or when the engine has been removed from service as a result of paragraph (f)(2) or (g)(2) of this AD.

(i) Credit for Previous Action

An initial or repetitive inspection performed before the effective date of this AD using RR ASB No. RB.211–72–AG456, dated September 9, 2010, satisfies the initial inspection requirement in paragraph (f) or repetitive inspection requirement in paragraph (g) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(k) Related Information

(1) For more information about this AD, contact Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *alan.strom@faa.gov;* phone: 781–238–7143; fax: 781–238–7199.

(2) Refer to European Aviation Safety Agency AD 2011–0080, dated May 6, 2011, for related information.

(l) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51.

(i) Rolls-Royce plc Alert Service Bulletin No. RB.211–72–AG456, Revision 1, dated November 4, 2011.

(ii) Rolls-Royce plc Alert Service Bulletin No. RB.211–72–AG456, dated September 9, 2010.

(2) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: 011 44 1332 242424; fax: 011 44 1332 249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* or Web: *https://www.aeromanager.com.*

(3) You may review copies of the service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(4) You may also review copies of the service information incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on February 22, 2012.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–5371 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0201; Directorate Identifier 2008–NE–47–AD; Amendment 39–16972; AD 2010–11–09R1]

RIN 2120–AA64

Airworthiness Directives; Thielert Aircraft Engines GmbH (TAE) Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are revising an existing airworthiness directive (AD) for TAE models TAE 125–01 and TAE 125–02–99 reciprocating engines installed on, but not limited to, Diamond Aircraft Industries Model DA 42 airplanes. That AD currently requires initial and repetitive replacements of proportional pressure reducing valves (PPRVs) (also known as propeller control valves). This new AD relaxes the repetitive replacement interval from a 300-hour interval to a 600-hour interval for PPRVs, P/N 05–7212–E002801, on TAE 125–02–99 engine. This AD was prompted by TAE increasing the life of the PPRV, part number (P/N) 05–7212–E002801, on TAE 125–02–99 engines from 300 to 600 hours. We are issuing this AD to prevent engine in-flight shutdown, possibly resulting in reduced control of the aircraft.

DATES: This AD is effective April 11, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of April 11, 2012.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of July 13, 2010 (75 FR 32253, June 8, 2010).

ADDRESSES: For service information identified in this AD, contact Thielert Aircraft Engines GmbH, Platanenstrasse 14 D–09350, Lichtenstein, Germany; phone: +49–37204–696–0; fax: +49–37204–696–2912; email: *info@centurion-engines.com.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7143; fax: 781–238–7199; email: *alan.strom@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to revise AD 2010–11–09, Amendment 39–16314 (75 FR 32253, June 8, 2010). That AD applies to the specified products. The NPRM published in the **Federal Register** on November 22, 2011 (76 FR 72128). That NPRM proposed to retain all of the requirements of AD 2010–11–09, except the repetitive replacement interval in paragraph (e)(2). This AD relaxes the repetitive 300-hour replacement interval to a 600-hour interval.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (76 FR 72128, November 22, 2011).

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

We estimate that this AD affects about 300 TAE 125–01 and TAE 125–02–99 reciprocating engines installed in Diamond Aircraft Industries Model DA 42 airplanes of U.S. registry. We also estimate that it will take 0.25 work-hour per engine to replace a PPRV and install a vibration isolator to the gearbox

assembly. The average labor rate is $85 per work-hour. Required parts cost about $275 per product. Based on these figures, we estimate the cost of the AD on U.S. operators to be $88,875.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2010–11–09, Amendment 39–16314 (75 FR 32253, June 8, 2010), and adding the following new AD:

2010–11–09R1 Thielert Aircraft Engines GmbH: Amendment 39–16972; Docket No. FAA–2009–0201; Directorate Identifier 2008–NE–47–AD.

(a) Effective Date

This AD is effective April 11, 2012.

(b) Affected ADs

This AD revises AD 2010–11–09, Amendment 39–16314 (75 FR 32253, June 8, 2010).

(c) Applicability

This AD applies to Thielert Aircraft Engines GmbH (TAE) models TAE 125–01 and TAE 125–02–99 reciprocating engines designated with part number (P/N) 05–7200–K000301 or 02–7200–14017R1. The engines are installed on, but not limited to, Diamond Aircraft Industries Model DA 42 airplanes.

(d) Unsafe Condition

This AD was prompted by engine in-flight shutdown incidents reported on Diamond Aircraft Industries DA 42 airplanes equipped with TAE 125 engines. The investigations showed that it was mainly the result of failure of the proportional pressure reducing valve (PPRV) (also known as the propeller control valve) due to high vibrations. Since the release of European Aviation Safety Agency (EASA) AD 2008–0145, the engine gearbox has been identified as the primary source of vibrations for the PPRV, and it has also been determined that failure of the electrical connection to the PPRV could have contributed to some power loss events or in-flight shutdowns. We are issuing this AD to prevent engine in-flight shutdown, possibly resulting in reduced control of the aircraft.

(e) Actions and Compliance

Unless already done, do the following actions.

(f) TAE 125–02–99 Reciprocating Engines

(1) Initial PPRV Replacement

For TAE 125–02–99 reciprocating engines with engine, P/N 05–7200–K000301, within 55 flight hours after the effective date of this AD:

(i) Replace the existing PPRV with PPRV, P/N 05–7212–E002801. Use paragraphs A. through B. of TAE Service Bulletin (SB) No. TM TAE 125–1007 P1, Revision 3, dated October 17, 2011, or SB No. TM TAE 125–1007 P1, Revision 2, dated April 29, 2009, to do the replacement.

(ii) Install a vibration isolator, P/N 05–7212–K022302, to the gearbox assembly. Use paragraphs 1 through 20 of TAE SB No. TM TAE 125–1009 P1, Revision 3, dated October 14, 2009, to do the installation.

(2) Repetitive PPRV Replacements

Thereafter, within every 600 flight hours, replace the PPRV, P/N 05–7212–E002801, with the same P/N PPRV.

(g) TAE 125–01 Reciprocating Engines

(1) Initial PPRV Replacement

For TAE 125–01 reciprocating engines with engine, P/N 02–7200–14017R1, within 55 flight hours after the effective date of this AD:

(i) Replace the existing PPRV with a PPRV, P/N NM–0000–0124501 or P/N 05–7212–K021401. Use paragraph 1 of TAE SB No. TM TAE 125–0018, Revision 1, dated November 12, 2008, to do the replacement.

(ii) Inspect the electrical connectors of the PPRV and replace the connectors if damaged, and install a vibration isolator, P/N 05–7212–K023801, to the gearbox assembly. Use paragraphs 1 through 27 of TAE SB No. TM TAE 125–0020, Revision 1, dated November 25, 2009, to do the inspection and installation.

(2) Repetitive PPRV Replacements

Thereafter, within every 300 flight hours, replace the PPRV with a PPRV, P/N NM–0000–0124501 or P/N 05–7212–K021401.

(h) FAA Differences

(1) We have found it necessary to not reference the second paragraph of the unsafe condition from the MCAI EASA AD 2009–0224. That sentence stated that the problem has only manifested itself on those TAE engines installed on Diamond Aircraft Industries DA 42 aircraft. The affected engines which require a PPRV could be used on other make and model airplanes in the future.

(2) We also did not reference the February 28, 2010 compliance date, which is in EASA AD 2009–0193R1, or the January 31, 2010 compliance date which is in EASA AD 2009–0224.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(j) Related Information

(1) Refer to EASA AD 2009–0224, dated October 20, 2009 (TAE 125–02–99), and EASA AD 2009–0193R1, dated December 1, 2009 (TAE 125–01), for related information.

(2) For more information about this AD, contact Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7143; fax: 781–238–7199; email: *alan.strom@faa.gov,* for more information about this AD.

(3) For service information identified in this AD, contact Thielert Aircraft Engines GmbH, Platanenstrasse 14 D–09350, Lichtenstein, Germany, phone: +49–37204–696–0; fax: +49–37204–696–2912; email: *info@centurion-engines.com*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on April 11, 2012.

(i) Thielert Aircraft Engines (TAE) GmbH, TAE Service Bulletin (SB) No. TM TAE 125–1007 P1, Revision 3, October 17, 2011.

(4) The following service information was approved for IBR on July 13, 2010 (75 FR 32253, June 8, 2010).

(i) Thielert Aircraft Engines (TAE) GmbH, TAE SB No. TM TAE 125–1007 P1, Revision 2, April 29, 2009.

(ii) Thielert Aircraft Engines (TAE) GmbH, TAE SB No. TM TAE 125–1009 P1, Revision 3, dated October 14, 2009.

(iii) Thielert Aircraft Engines (TAE) GmbH, TAE SB No. TM TAE 125–0020, including Annexes A and B, Revision 1, dated November 25, 2009.

(iv) Thielert Aircraft Engines (TAE) GmbH, TAE SB No. TM TAE 125–0018, Revision 1, dated November 12, 2008.

(5) For service information identified in this AD, contact Thielert Aircraft Engines GmbH, Platanenstrasse 14 D–09350, Lichtenstein, Germany, phone: +49–37204–696–0; fax: +49–37204–696–2912; email: *info@centurion-engines.com.*

(6) You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(7) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr_locations.html.*

Issued in Burlington, Massachusetts, on February 24, 2012.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–5372 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 34–66502]

Rules of Organization; Conduct and Ethics; and Information and Requests

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; technical amendment.

SUMMARY: The Securities and Exchange Commission (''SEC'' or ''Commission'') is making technical amendments to the rule under which former members and employees of the Commission are required to file with the Commission a statement concerning their practice outside the government. The amendments change the office responsible for processing these statements and provide a means of filing a statement electronically.

DATES: *Effective:* March 7, 2012.

FOR FURTHER INFORMATION CONTACT: Shira Pavis Minton, Ethics Counsel, 202–551–7938, Office of the Ethics Counsel, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–9150.

SUPPLEMENTARY INFORMATION:

I. Background

SEC Conduct Rule 8(b) [1] requires that any former member or employee of the Commission who, within 2 years after ceasing to be such, is employed or retained as the representative of any person outside the government in any matter in which it is contemplated that he or she will appear before the Commission, or communicate with the Commission or its employees, shall, within ten days of such retainer or employment, or of the time when appearance before, or communication with the Commission or its employees is first contemplated, file with the Secretary of the Commission a statement which includes: (i) A description of the contemplated representation; (ii) An affirmative representation that the former employee while on the Commission's staff had neither personal and substantial responsibility nor official responsibility for the matter which is the subject of the representation; and (iii) The name of the Commission Division or Office in which the person had been employed.

In order to increase efficiency, the Commission is adopting a technical amendment to require that SEC conduct rule 8(b) submissions be sent to the Office of the Ethics Counsel rather than the Secretary of the Commission and provide a means of filing a statement electronically.[2]

II. Administrative Law Matters

Under the Administrative Procedure Act, notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest. The amendments are technical changes, adopted solely to update references to a statutory provision that remains unchanged except for its designation. For this reason, the Commission finds that it is unnecessary to publish notice of these amendments. Similarly, the amendments do not require analysis under the Regulatory Flexibility Act or analysis of major rule status under the Small Business Regulatory Fairness Act. For purposes of Regulatory Flexibility Act analysis, the term ''rule'' means any rule for which the agency publishes a general notice of proposed rulemaking, and for purposes of Congressional review of agency rulemaking, the term ''rule'' does not include any rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.[3] Because these rules relate solely to the agency's organization, procedure, or practice and do not substantially affect the rights or obligations of non-agency parties, they are not subject to the Small Business Regulatory Enforcement Fairness Act.[4] Finally, these amendments do not contain any new collection of information requirements as defined by the Paperwork Reduction Act of 1995, as amended.[5]

III. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. The amendments adopted today are technical in nature and will produce the benefit of facilitating the efficient operation of the Commission. The Commission also believes that these rules will not impose any costs on non-agency parties, or that if there are any such costs, they are negligible.

IV. Consideration of Burden on Competition

Section 23(a)(2) [6] of the Exchange Act requires the Commission, in adopting rules under the Exchange Act, to consider the competitive effects of such rules. Because this amendment merely makes technical changes to an existing requirement, no competitive advantages or disadvantages would be created.

V. Statutory Authority and Text of Amendments

We are adopting these technical amendments under the authority set forth in Section 23(a) [7] of the Exchange Act.

[1] 17 CFR 200.735–8(b)(1).

[2] 17 CFR 200.735–8(b)(1).

[3] 5 U.S.C. 601(2) and 5 U.S.C. 804(3)(C).

[4] 5 U.S.C. 804.

[5] 44 U.S.C. 3501–3520.

[6] 17 CFR 240.23(a)(2).

[7] 17 CFR 240.23(a).

List of Subjects 17 CFR Part 200

Administrative practice and procedure, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

Text of Amendments

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 200—RULES OF ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart M—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

■ 1. The authority citation for Part 200, Subpart M, continues to read in part as follows:

Authority: 15 U.S.C. 77s, 77sss, 78w, 80a–37, 80b–11; E.O. 11222, 3 CFR, 1964–1965 Comp., p. 36; 5 CFR 735.104; 5 CFR 2634; and 5 CFR 2635, unless otherwise noted.

■ 2. Section 200.735–8 is amended as follows:

■ a. In paragraph (b)(1) introductory text by removing the phrase ''Secretary of the Commission'' and adding in its place ''Office of the Ethics Counsel'';

■ b. Paragraph (b)(2) is redesignated as paragraph (b)(3) and new paragraph (b)(2) is added to read as follows:

§ 200.735–8 Practice by former members and employees of the Commission.

* * * * *

(b) * * *

(2) The statement required by paragraph (b)(1) of this section may be filed electronically based on instructions provided by the Office of the Ethics Counsel at *www.sec.gov*, or filed in paper by mailing to the U.S. Securities & Exchange Commission, Office of the Ethics Counsel, 100 F Street NE., Washington, DC 20549–9150.

* * * * *

Dated: March 1, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–5454 Filed 3–6–12; 8:45 am]

BILLING CODE 8011–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2010–1036; FRL–9643–2]

Approval and Promulgation of Implementation Plans and Designations of Areas for Air Quality Planning Purposes; Georgia; Atlanta; Determination of Attainment by Applicable Attainment Date for the 1997 8-Hour Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is determining that the Atlanta, Georgia, 1997 8-hour ozone nonattainment Area (hereafter referred to as ''the Atlanta Area'' or ''the Area'') has attained the 1997 8-hour ozone national ambient air quality standards (NAAQS) by its applicable attainment date of June 15, 2011. The determination of attainment was made by EPA on June 23, 2011, and was based on quality-assured and certified monitoring data for the 2008–2010 monitoring period. The Atlanta Area is comprised of Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta, Dekalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Hall, Henry, Newton, Paulding, Rockdale, Spalding and Walton Counties in Georgia. In this action EPA is determining that the above-identified Area attained the 1997 8-hour ozone NAAQS by its applicable attainment date. EPA is finalizing this action because it is consistent with the Clean Air Act (CAA) and its implementing regulations. Additionally, in this action EPA is clarifying an inadvertent citation error in the proposed approval for this action.

DATES: This final rule is effective on April 6, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R04–OAR–2010–1036. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.

FOR FURTHER INFORMATION CONTACT: For information regarding this attainment determination, contact Mr. Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Telephone number: (404) 562–9043; email address: *lakeman.sean@epa.gov.* For information regarding 8-hour ozone NAAQS, contact Ms. Jane Spann, Regulatory Development Section, at the same address above. Telephone number: (404) 562–9029; email address: *spann.jane@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

Based on EPA's review of the quality-assured and certified monitoring data for 2008–2010, and in accordance with section 181(b)(2) of the CAA and EPA's regulations, EPA is determining that the Atlanta Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011.[1]

On June 23, 2011, EPA published a determination of attainment for the Atlanta Area, which served to suspend the requirements for the State to submit an attainment demonstration and associated reasonably available control measures (RACM), reasonable further progress (RFP) plan, contingency measures, and other planning State Implementation Plan (SIP) revisions related to attainment of the 1997 8-hour ozone NAAQS so long as the Area continues to attain the 1997 8-hour ozone NAAQS. *See* 76 FR 36873. This final rulemaking also includes useful background information on the 8-hour ozone NAAQS relevant to the Atlanta Area. Today's action finalizes EPA's determination that the Atlanta Area attained the 1997 8-hour ozone NAAQS

[1] Effective June 15, 2004, EPA designated the Atlanta Area as a marginal area under the 1997 8-hour ozone NAAQS. Subsequently, EPA took action to reclassify the Area to moderate for the 1997 8-hour ozone NAAQS. Moderate areas for the 1997 8-hour ozone NAAQS had an applicable attainment date of June 15, 2010, unless the area qualified for an extension. On November 30, 2010, EPA took final action to extend the applicable attainment date for the Atlanta Area to June 15, 2011. *See* 75 FR 73969 for more information.

by the applicable attainment date of June 15, 2011. Today's action is simply focused on the date by which the Area had attaining data.

Other specific requirements of the determination and the rationale for EPA's action are explained in the notice of proposed rulemaking (NPR) published on December 15, 2011 (76 FR 77950). The comment period for this action closed on January 17, 2012. No comments were received in response to the NPR.

Also, in the NPR, EPA stated that its obligations to determine if an area attained the 1997 8-hour NAAQS by its applicable attainment date were found under CAA section 179(c). *See* 76 FR at 77951–77952. The citation to section 179(c) was incorrect. EPA notes that for an area such as Atlanta, which is designated moderate nonattainment for the 1997 8-hour ozone standard, the proper citation is CAA section 181(b)(2)(A). Thus CAA section 181(b)(2) is the correct citation for the basis of today's action.

II. What is the effect of this action?

Today's action is a determination that the Atlanta Area attained the 1997 8-hour ozone NAAQS by its applicable attainment date of June 15, 2011, consistent with CAA section 181(b)(2). Finalizing this action does not constitute a redesignation of Atlanta Area to attainment of the 1997 8-hour ozone NAAQS under section 107(d)(3) of the CAA. Further, finalizing this action does not involve approving maintenance plans for the Atlanta Area as required under section 175A of the CAA, nor would it find that the Atlanta Area has met all other requirements for redesignation. The designation status of the Atlanta Area remains nonattainment for the 1997 8-hour ozone NAAQS until such time as EPA determines that the Area meets the CAA requirements for redesignation to attainment and takes action to redesignate the Area.

III. What is EPA's final action?

EPA is determining, based on quality-assured and certified monitoring data for the 2008–2010 monitoring period, that the Atlanta Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011. This action is being taken pursuant to section 181(b)(2) of the CAA and is consistent with the CAA and its implementing regulations.

IV. Statutory and Executive Order Reviews

This action makes a determination of attainment by the applicable attainment date, based on air quality, and would not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this 1997 8-hour ozone determination of attainment by applicable attainment date for the Atlanta Area does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 7, 2012. Filing a petition for reconsideration by the Administrator of these final rules do not affect the finality of these actions for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 22, 2012.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart L—Georgia

■ 2. Section 52.577 is amended by adding paragraph (d) to read as follows:

§ 52.577 Determination of attainment.

* * * * *

(d) Based upon EPA's review of the air quality data for the 3-year period 2008–2010, EPA determined that the Atlanta, Georgia, 1997 8-hour ozone nonattainment Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011. Therefore, EPA has met the requirement pursuant to CAA section 181(b)(2) to determine, based on the Area's air quality as of the attainment date, whether the Area attained the standard. EPA also determined that the Atlanta, Georgia, 1997 8-hour ozone nonattainment Area is not subject to the consequences of

failing to attain pursuant to section 181(b)(2).

[FR Doc. 2012–5381 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2011–0029; FRL–9643–3]

Approval and Promulgation of Implementation Plans and Designations of Areas for Air Quality Planning Purposes; North Carolina and South Carolina; Charlotte; Determination of Attainment by Applicable Attainment Date for the 1997 8-Hour Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is determining that the bi-state Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina, 1997 8-hour ozone nonattainment Area (hereafter referred to as ''the bi-state Charlotte Area'' or ''the Area'') has attained the 1997 8-hour ozone national ambient air quality standards (NAAQS) *by its applicable attainment date of June 15, 2011.* The determination of attainment was made by EPA on November 15, 2011, and was based on quality-assured and certified monitoring data for the 2008–2010 monitoring period. The bi-state Charlotte Area is comprised of Cabarrus, Gaston, Lincoln, Mecklenburg, Rowan, Union and a portion of Iredell (Davidson and Coddle Creek Townships) Counties in North Carolina; and a portion of York County in South Carolina. In this action EPA is determining to find that the above-identified Area attained the 1997 8-hour ozone NAAQS by its applicable attainment date. EPA is finalizing this action because it is consistent with the Clean Air Act (CAA) and its implementing regulations. Additionally, in this action EPA is clarifying an inadvertent citation error in the proposed approval for this action.

DATES: *Effective Date:* This final rule is effective on April 6, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R04–OAR–2011–0029. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.

FOR FURTHER INFORMATION CONTACT: For information regarding this attainment determination, contact Mr. Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Telephone number: (404) 562–9043; email address: *lakeman.sean@epa.gov.* For information regarding 8-hour ozone NAAQS, contact Ms. Jane Spann, Regulatory Development Section, at the same address above. Telephone number: (404) 562–9029; email address: *spann.jane@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

Based on EPA's review of the quality-assured and certified monitoring data for 2008–2010, and in accordance with section 181(b)(2) of the CAA and EPA's regulations, EPA is determining that the bi-state Charlotte Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011.[1]

On November 15, 2011, EPA published a final rulemaking for the bi-state Charlotte Area which served to suspend the requirements for the State to submit an attainment demonstration and associated reasonably available control measures (RACM), reasonable further progress (RFP) plan, contingency measures, and other planning State Implementation Plan (SIP) revisions related to attainment of the 1997 8-hour ozone NAAQS so long as the Area continues to attain the 1997 8-hour ozone NAAQS. *See* 76 FR 70656. This final rulemaking also includes useful background information on the 8-hour ozone NAAQS relevant to the bi-state Charlotte Area. Today's action finalizes EPA's determination that the bi-state Charlotte Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011. Today's action is simply focused on the date by which the Area had attaining data.

Other specific requirements of the determination and the rationale for EPA's action are explained in the notice of proposed rulemaking (NPR) published on December 29, 2011 (76 FR 81901). The comment period closed on January 30, 2012. No comments were received in response to the NPR.

Also, in the NPR, EPA stated that its obligations to determine if an area attained the 1997 8-hour NAAQS by its applicable attainment date were found under CAA section 179(c). See 76 FR 81902. The citation to section 179(c) was incorrect. EPA notes that for an area such as Charlotte, which is designated moderate nonattainment for the 1997 8-hour ozone standard, the proper citation is CAA section 181(b)(2)(A). Thus CAA section 181(b)(2) is the correct citation for the basis of today's action.

II. What is the effect of this action?

Today's action is a determination that the bi-state Charlotte Area attained the 1997 8-hour ozone NAAQS by its applicable attainment date of June 15, 2011, consistent with CAA section 181(b)(2). Finalizing this action does not constitute a redesignation of bi-state Charlotte Area to attainment of the 1997 8-hour ozone NAAQS under section 107(d)(3) of the CAA. Further, finalizing this action does not involve approving maintenance plans for the bi-state Charlotte Area as required under section 175A of the CAA, nor would it find that the bi-state Charlotte Area has met all other requirements for redesignation. The designation status of the bi-state Charlotte Area remains nonattainment for the 1997 8-hour ozone NAAQS until such time as EPA determines that the Area meets the CAA requirements for redesignation to attainment and takes action to redesignate the Area.

III. What is EPA's final action?

EPA is determining, based on quality-assured and certified monitoring data for the 2008–2010 monitoring period, that the bi-state Charlotte Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011. This action is being taken pursuant to section 181(b)(2) of the CAA

[1] Effective June 15, 2004, EPA designated the bi-state Charlotte Area as a moderate area under the 1997 8-hour ozone NAAQS. Moderate areas for the 1997 8-hour ozone NAAQS had an applicable attainment date of June 15, 2010, unless the Area qualified for an extension. On May 31, 2011, EPA took final action to extend the applicable attainment date for the bi-state Charlotte Area to June 15, 2011. *See* 76 FR 31245 for more information.

and is consistent with the CAA and its implementing regulations.

IV. Statutory and Executive Order Reviews

This action makes a determination of attainment by the applicable attainment date, based on air quality, and would not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this determination of attainment by the attainment date for the 1997 8-hour ozone NAAQS final approval for the bi-state Charlotte Area does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the determination does not have substantial direct effects on an Indian Tribe. The Catawba Indian Nation Reservation is located within the South Carolina portion of the bi-state Charlotte nonattainment area. Generally SIPs do not apply in Indian country throughout the United States. However, for purposes of the Catawba Indian Nation Reservation in Rock Hill, the South Carolina SIP does apply within the Reservation. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120, ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' Pursuant to Executive Order 13175 and the EPA Policy on Consultation and Coordination with Indian Tribes, in a letter dated October 13, 2011, EPA extended the opportunity for consultation between EPA and Catawba. Consultation with the Catawba Tribe began on October 14, 2011, and ended on October 31, 2011. The views and concerns raised by the Catawba Indian Nation during consultation have been taken into account in this final rule. Furthermore, EPA notes today's action will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 7, 2012. Filing a petition for reconsideration by the Administrator of these final rules do not affect the finality of these actions for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 22, 2012.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart II—North Carolina

■ 2. Section 52.1779 is amended by adding paragraph (b) to read as follows:

§ 52.1779 Control strategy: Ozone.

* * * * *

(b) Based upon EPA's review of the air quality data for the 3-year period 2008–2010, EPA determined that the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina, 1997 8-hour ozone nonattainment Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011. Therefore, EPA has met the requirement pursuant to CAA section 181(b)(2) to determine, based on the Area's air quality as of the attainment date, whether the Area attained the standard. EPA also determined that the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina, 1997 8-hour ozone nonattainment Area is not subject to the consequences of failing to attain pursuant to section 181(b)(2).

Subpart PP—South Carolina

■ 3. Section 52.2125 is amended by adding paragraph (b) to read as follows:

§ 52.2125 Control strategy: Ozone.

* * * * *

(b) Based upon EPA's review of the air quality data for the 3-year period 2008–2010, EPA determined that the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina, 1997 8-hour ozone nonattainment Area attained the 1997 8-hour ozone NAAQS by the applicable attainment date of June 15, 2011. Therefore, EPA has met the requirement pursuant to CAA section 181(b)(2) to determine, based on the Area's air quality as of the attainment date, whether the Area attained the standard. EPA also determined that the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina, 1997 8-hour ozone nonattainment Area is not subject to the consequences of failing to attain pursuant to section 181(b)(2).

[FR Doc. 2012–5384 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2011–0875; FRL–9626–6]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on November 22, 2011 and concern particulate matter (PM) emissions from paved and unpaved roads and livestock operations and aggregate and related operations. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: *Effective Date:* This rule is effective on April 6, 2012.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2011–0875 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps, multi-volume reports), and some may not be available in either location (e.g., confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, (415) 947–4125, *vineyard.christine@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. Proposed Action

On November 22, 2011 (76 FR 72142), EPA proposed to approve the following rules into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
SCAQMD	1157	PM_{10} Emission Reduction from Aggregate and Related Operations.	09/06/06	05/17/10
SCAQMD	1186	PM_{10} Emissions from Paved and Unpaved Roads and Livestock Operations.	07/11/08	12/23/08

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted that change our assessment that the submitted rules comply with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving these rules into the California SIP.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**.

This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 7, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: January 13, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52 [AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(364)(i)(B)(*2*) and (379)(i)(A)(*5*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(364) * * *

(i) * * *

(B) * * *

(*2*) Rule 1186, ''PM_{10} Emissions from Paved and Unpaved Roads and Livestock Operations,'' amended on July 11, 2008.

* * * * *

(379) * * *

(i) * * *

(A) * * *

(*5*) Rule 1157, ''PM_{10} Emission Reductions from Aggregate and Related Operations,'' adopted on September 6, 2006.

* * * * *

[FR Doc. 2012–5385 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2009–0596; FRL–9637–1]

RIN 2040–AF36

Effective Date for the Water Quality Standards for the State of Florida's Lakes and Flowing Waters

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; delay of effective date.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing an extension of the March 6, 2012 effective date of the ''Water Quality Standards for the State of Florida's Lakes and Flowing Waters; Final Rule'' (inland waters rule) for four months to July 6, 2012. EPA's inland waters rule included an effective date of March 6, 2012 for the entire regulation except for the site-specific alternative criteria provision, which took effect on February 4, 2011. This revision of the effective date for the inland waters rule does not affect or change the February 4, 2011 effective date for the site-specific alternative criteria provision.

DATES: This final rule is effective on March 6, 2012. The effective date of § 131.43, revised on December 6, 2010 (75 FR 75805), effective March 6, 2012, is delayed until July 6, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–OW–2011–0466. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information of which disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center, EPA West Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004, Attention: Docket ID No. EPA–HQ–OW–2009–0596. The Office of Water (OW) Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The OW Docket Center telephone number is 202–566–1744. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744.

FOR FURTHER INFORMATION CONTACT: For information concerning this rulemaking, contact: Tracy Bone, U.S. EPA, Office of Water, Mailcode 4305T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number 202–564–5257; email address: *bone.tracy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

Does this action apply to me?

Citizens concerned with water quality in Florida may be interested in this rulemaking. Entities discharging nitrogen or phosphorus to lakes and flowing waters of Florida could be indirectly affected by this rulemaking because water quality standards (WQS) are used in determining National Pollutant Discharge Elimination System (NPDES) permit limits. Categories and entities that may ultimately be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging pollutants to lakes and flowing waters in the State of Florida.
Municipalities	Publicly-owned treatment works discharging pollutants to lakes and flowing waters in the State of Florida.
Stormwater Management Districts	Entities responsible for managing stormwater runoff in Florida.

This table is not intended to be exhaustive, but rather provides a guide for entities that may be directly or indirectly affected by this action. This table lists the types of entities of which EPA is now aware that potentially could be affected by this action. Other types of entities not listed in the table, such as nonpoint source contributors to nitrogen/phosphorus pollution in Florida's waters may be indirectly affected through implementation of Florida's water quality standards program (i.e., through Basin Management Action Plans (BMAPs)).

Any parties or entities conducting activities within watersheds of the Florida waters covered by this rule, or who rely on, depend upon, influence, or contribute to the water quality of the lakes and flowing waters of Florida, may be indirectly affected by this rule. To determine whether your facility or activities may be affected by this action, you should carefully examine the language in 40 CFR 131.43, which is the final rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

On December 6, 2010, EPA's final inland waters rule, entitled ''Water Quality Standards for the State of Florida's Lakes and Flowing Waters; Final Rule,'' was published in the **Federal Register** at 75 FR 75762, and codified at 40 CFR 131.43. The final inland waters rule established numeric nutrient criteria in the form of total nitrogen, total phosphorus, nitrate+nitrite, and chlorophyll a for the different types of Florida's inland waters to assure attainment of the State's applicable water quality designated uses. More specifically, the numeric nutrient criteria translated Florida's narrative nutrient provision at Subsection 62–302–530(47)(b), Florida Administrative Code (F.A.C.), into numeric values that apply to lakes and springs throughout Florida and flowing waters outside of the South Florida Region. (EPA has distinguished the South Florida Region as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake Okeechobee.) This final inland waters rule seeks to improve water quality, protect public health and aquatic life, and achieve the long-term recreational uses of Florida's waters, which are a critical part of the State's economy.

III. Revised Effective Date

A. Rationale for Extending the March 6, 2012 Effective Date

As stated in the inland waters rule, 75 FR 75807, the rule was scheduled to take effect on March 6, 2012, except for the site-specific alternative criteria (SSAC) provision at 40 CFR 131.43(e), which took effect on February 4, 2011. As discussed at length in the proposal to this final rule, 76 FR 79604 and finalized in this action, EPA is extending the effective date of the final inland waters rule four months to July 6, 2012.

The State rulemaking and legislative process is ongoing and its ultimate resolution is uncertain. The Florida Department of Environmental Protection (FDEP) sent the Environmental Review Commission (ERC)-approved rules and amendments to the Florida legislature for ratification during the 2012 regular legislative session. The last day of Florida's 2012 regular legislative session is March 9, 2012. Final State action on Florida numeric nutrient criteria that assure attainment of State water quality designated uses consistent with applicable CWA provisions could affect the need for EPA's criteria for corresponding waters to take effect. Implementation of either the State or Federal criteria could have implications for many interested parties and members of the public in the State.

Extending the effective date of EPA's inland waters rule would avoid the confusion and inefficiency that may occur should Federal criteria become effective while State criteria are being finalized by the State, submitted to EPA, and reviewed by EPA. To this end, EPA proposed a 90-day extension of the March 6, 2012 effective date on December 22, 2012 (76 FR 79604) and requested comment. EPA also requested comment on whether a longer extension should be provided. Based on public comment, and because the State rulemaking process has continued toward FDEP's adoption and submission of new or revised water quality standards to EPA for review pursuant to CWA section 303(c), EPA is extending the March 6, 2012 effective date by four months to July 6, 2012 to allow the State to complete its process.

B. Public Comment

EPA received six comments on the proposed rule. One commenter does not support any delay in the effective date. This commenter says that an extension is inconsistent with EPA's determination that numeric nutrient criteria are necessary for Florida, the Clean Water Act's direction to EPA to act promptly in establishing such criteria following such determination, and a consent decree obligation. EPA disagrees with the commenter. EPA maintains that its determination remains in place and that numeric nutrient criteria for Florida were promptly proposed and promulgated by EPA (75 FR 75762, December 10, 2010), consistent with EPA's determination, the CWA, and the consent decree. This action provides a limited time for the State of Florida to complete its current rulemaking process and to submit any finally adopted water quality standards to EPA for review under the Clean Water Act. As mentioned above, having EPA's criteria take effect while State criteria are being finalized by the State in the near term could cause confusion and administrative inefficiency for the State and regulated entities, something the EPA wants to avoid. Providing this time to allow the State rulemaking process to conclude will avoid such confusion and inefficiency.

The other five commenters support the proposal to extend the effective date, arguing that the additional time would avoid the confusion and inefficiency that may occur should Federal criteria become effective while State criteria are being finalized by the State, and possibly being reviewed by EPA. These commenters supported the proposed extension of the effective date by 90 days. In addition to extending the effective date by 90 days, some of these commenters also proposed that EPA extend the comment period for longer than 90 days; a six-month extension and a seven-month extension were mentioned specifically. EPA agrees that a slightly longer extension is warranted, but that four months is appropriate in order to provide sufficient time to allow the State rulemaking process to come to completion.

Therefore, based on public comment as well as the continued progress by Florida in their water quality standards process, EPA believes that a four-month extension is warranted.

EPA received a comment urging actions related to an EPA rulemaking under development (i.e., not the inland waters rule). These comments are outside the scope of this action and therefore EPA is not addressing them.

C. Good Cause Exemption

Section 553(d)(3) of the Administrative Procedure Act, 5 U.S.C. 553(d)(3), provides that ''[t]he required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except * * * (3) as otherwise provided by the agency for good cause found and published with the rule.'' Today's final rule is a rule that relieves a restriction, i.e., that delays the effective date of a Federal rule. Today's rule does not establish any requirements but rather merely extends the effective date of already-promulgated requirements. On this basis, EPA has determined that there is ''good cause'' for having this rule take effect upon March 6, 2012. EPA thus finds that this constitutes ''good cause'' under 5 U.S.C. 553(d)(3).

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993), since it merely extends the effective date of an already promulgated rule, and is therefore not subject to review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). This action does not impose any information collection burden, reporting or record keeping requirements on anyone.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this action on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

This final rule does not establish any requirements that are applicable to small entities, but rather merely extends the date of already promulgated requirements. Thus, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives, and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. This final rule does not regulate or affect any entity and, therefore, is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132 (Federalism)

This action does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action merely extends the effective date of an already promulgated regulation.

F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

Subject to the Executive Order 13175 (65 FR 67249, November 9, 2000) EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement. However, the rule will neither impose substantial direct compliance costs on Tribal governments, nor preempt Tribal law.

In the State of Florida, there are two Indian Tribes, the Seminole Tribe of Florida and the Miccosukee Tribe of Indians of Florida, with lakes and flowing waters. Both Tribes have been approved for treatment in the same manner as a State (TAS) status for CWA sections 303 and 401 and have federally-approved WQS in their respective jurisdictions. These Tribes are not subject to this final rule. This rule will not impact the Tribes because it merely extends the date of already promulgated requirements.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866 and because the Agency does not believe this action includes environmental health risks or safety risks that would present a risk to children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g.,

materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (E.O.) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. This action is not subject to E.O. 12898 because this action merely extends the effective date for already promulgated requirements.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of March 6, 2012. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 131

Environmental protection, Water quality standards, Nitrogen/phosphorus pollution, Nutrients, Florida.

Dated: February 16, 2012.

Lisa P. Jackson,

Administrator.

[FR Doc. 2012–5604 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0702; FRL–9339–7]

Fenamiphos; Data Call-in Order for Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final order.

SUMMARY: This order requires the submission of various data to support the continuation of the tolerances for the pesticide fenamiphos. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA). Following publication of this order, persons who are interested in the continuation of the fenamiphos tolerances must notify the Agency by completing and submitting the required section 408(f) Order Response Form (available in the docket) within 90 days. If the Agency does not receive within 90 days after publication of the final order a section 408(f) Response Form identifying a person who agrees to submit the required data, EPA will revoke the fenamiphos tolerances.

DATES: This final order is effective March 7, 2012. A section 408(f) Order Response Form must be received on or before June 5, 2012.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0702. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

Submit your section 408(f) Order Response Form, identified by docket identification (ID) number EPA–HQ–OPP–2011–0702, by one of the following methods:

- *Federal eRulemaking Portal:* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.
- *Instructions:* Direct your section 408(f) Order Response Form to docket ID number EPA–HQ–OPP–2011–0702. EPA's policy is that all information and comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the information or comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send information or comments via an email directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the information or comment that is placed in the docket and made available on the Internet. If you submit information or a comment electronically, EPA recommends that you include your name and other contact information in the body of your information or comment and with any disk or CD–ROM you submit. If EPA cannot read your information or comment due to technical difficulties and cannot contact

you for clarification, EPA may not be able to consider your submission. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

• *Docket:* All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Eric Miederhoff, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8028; email address: *miederhoff.eric@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines,'' which is listed under ''Documents related to our mission.''

II. Background

A. What action is the agency taking?

In this document EPA is issuing an order requiring the submission of various data to support the continuation of the fenamiphos tolerances at 40 CFR 180.349 under section 408 of the FFDCA, 21 U.S.C. 346a.

Fenamiphos is not currently registered under FIFRA, 7 U.S.C. 136 *et seq.* The FIFRA registration for fenamiphos was canceled in 2007. However, four FFDCA tolerances remain for residues of fenamiphos on the following commodities: Bananas, grapes, pineapples, and raisins (40 CFR 180.349). Since there are currently no domestic registrations for fenamiphos, these tolerances are referred to as ''import tolerances.'' It is these tolerances that are addressed by the data call-in order.

B. What is the agency's authority for taking this action?

Under section 408(f) of the FFDCA, EPA is authorized to require, by order, submission of data ''reasonably required to support the continuation of a tolerance'' when such data cannot be obtained under the Data Call-In authority of FIFRA section 3(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603. A FFDCA section 408 data call-in order may only be issued following publication of notice of the order and a 60-day public comment provision.

A section 408(f) Data Call-In order must contain the following elements:

1. A requirement that one or more persons submit to EPA a notice identifying the person(s) who commit to submit the data required in the order;

2. A description of the required data and the required reports connected to such data;

3. An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA; and

4. The required submission date for the notice identifying one or more interested persons who commit to submit the required data and the required submission dates for all the data and reports required in the order. (21 U.S.C. 346a(f)(1)(C)).

EPA may by order modify or revoke the affected tolerances if any one of the following submissions is not made in a timely manner:

i. A notice identifying the one or more interested persons who commit to submit the data;

ii. The data itself; or

iii. The reports required under a section 408(f) order are not submitted by the date specified in the order. (21 U.S.C. 346a(f)(2)).

C. What preliminary steps were taken by EPA prior to issuing this final order?

On August 31, 2011, EPA issued a proposed data call-in order for the pesticide fenamiphos in connection with tolerances for that pesticide under section 408 of the FFDCA, 21 U.S.C. 346a. (75 FR 44181). The proposed data call-in order included the following studies:

1. Comparative Cholinesterase Assay (Non-Guideline).

2. Immunotoxicity Study (870.7800).

3. Crop Field Trials (860.1500)— (grapes; foliar use in Mexico).

III. Summary of Public Comments Received and Agency Response to Comments

EPA received one comment in response to the August 31, 2011, **Federal Register** notice announcing the Agency's proposed data call-in order for fenamiphos (76 FR 54185; FRL–8886–2). However, this comment merely argued that there are too many toxic chemicals approved for use in the United States and did not, in any manner, address the Agency's intention to issue a data call-in order for fenamiphos. Therefore, no response to this comment is needed. In addition, the Agency has not received any of the data identified in the proposed order as needed to support the fenamiphos tolerances.

IV. Final Data Call-in Order

Because no comments were submitted on the proposal and the data deficiencies identified in the proposed order remain, EPA is issuing this final data call-in order under FFDCA section 408(f)(1)(C) for fenamiphos in the same form as the proposed order and for the reasons set forth in that proposed order. Specifically, this order:

1. Requires Notice of Intent to Submit Data. A notice identifying the person or

persons who commit to submit the data and reports in accordance with Unit V.2. must be submitted to EPA if any person wishes to support the fenamiphos tolerances. The notice must be submitted on a section 408(f) Order Response Form which is available in the electronic docket, *http://www.regulations.gov,* under docket ID number EPA–HQ–OPP–2011–0702.

2. Establishes a Deadline for Submission of Notice Identifying Data Submitters. The notice described in Unit V.1. identifying data submitters must be submitted to and received by EPA on or before June 5, 2012. Instructions on methods for submitting this notice (referred to in this order as a ''section 408(f) Order Response Form'') are set out under **ADDRESSES.**

3. Describes Data and Reports Required to Support Continuation of the Fenamiphos Tolerances, Requires Submission of Those Data and Reports, and Establishes Deadlines for Submission. The table in this Unit describes the data and reports required to be submitted on fenamiphos under this order and the deadlines for the submission of each study and report. The required submission date is calculated from June 5, 2012. Thus, for example, if EPA generally allows 12 months to complete a study, the required submission date for such a study under this order would be 15 months from the date of publication of the order in the **Federal Register**.

OCSPP Harmonized guideline No.	Study title	Timeframe for protocol report submission	Timeframe for data submission
Non-Guideline	Comparative Cholinesterase Assay	12/7/2012	6/7/2013
870.7800	Immunotoxicity Study	12/7/2012	6/7/2013
860.1500	Crop Field Trials (grapes; foliar use in Mexico)	Not Required	6/9/2014

EPA provided a description of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA in the proposed order and relies on that description in this final order.

V. Failure To Submit Notice of Intent To Submit Data or Data and Reports

If, by June 5, 2012 the Agency does not receive a section 408(f) Order Response Form identifying a person who agrees to submit the required data, EPA will revoke the fenamiphos tolerances at 40 CFR 180.349. Such revocation is subject to the objection and hearing procedure in FFDCA section 408(g)(2) but the only material issue in such a procedure is whether a submission required by the order was made in a timely fashion.

Additional events that may be the basis for modification or revocation of fenamiphos tolerances include, but are not limited to the following:

1. No person submits on the required schedule an acceptable protocol report when such report is required to be submitted to the Agency for review.

2. No person submits on the required schedule acceptable data as required by the final order.

VI. Statutory and Executive Order Reviews

This action, which requires the submission of data in support of tolerances in accordance with FFDCA section 408, is in the form of an order and not a rule. (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act (APA), orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on a rulemaking do not apply to this action, as explained further in the following discussion.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Because this order is not a ''regulatory action'' as that term is defined in Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not subject to review by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose additional burdens that require approval by OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). The information collection activities associated with the order requesting data from any party interested in supporting certain tolerances are already approved by OMB under OMB Control No. 2070–0174, and are identified by EPA ICR No. 2288.01. Burden is defined at 5 CFR 1320.3(b). Under the PRA, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

C. Regulatory Flexibility Act

Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

D. Unfunded Mandates Reform Act; Executive Order 13132: Federalism; and Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This order requests data from any party interested in supporting certain tolerances and does not impose obligations on any person or entity including States or tribes; nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132 (64 FR 43255, August 10, 1999) and Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538).

E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks; Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use; and Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

As indicated previously, this action is not a ''regulatory action'' as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) and Executive Order 13211 (66 FR 28355, May 22, 2001). In addition, this order also does not require any special considerations under Executive Order 12898 (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), (15 U.S.C. 272 note). The Congressional Review Act, 5 U.S.C. 801 *et seq.* does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Fenamiphos, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 24, 2012.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2012–5383 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0659; FRL–9336–6]

Pyriofenone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, including its metabolites and degradates, in or on grape and grape, raisin. ISK BioSciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 7, 2012. Objections and requests for hearings must be received on or before May 7, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0659. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Heather Garvie, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0034; email address: *garvie.heather@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0659 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 7, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0659, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S.

Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 8, 2010 (75 FR 54629) (FRL–8843–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E7731) by ISK BioSciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide pyriofenone (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, in or on grape at 0.2 parts per million (ppm).

That notice referenced a summary of the petition prepared by ISK BioSciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.*

There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has modified the petitioned for tolerance for pyriofenone by increasing the tolerance level for grape and establishing a separate tolerance for grape, raisin. The reasons for these changes are explained in Unit IV.D.

These are the first tolerances established for pyriofenone. There are no registered uses for pyriofenone in the United States. The tolerances were requested in connection with use of pyriofenone on grapes grown overseas. These tolerances will allow grapes and processed grape commodities containing pyriofenone residues to be imported to the United States.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyriofenone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyriofenone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The liver and kidney were affected by treatment with pyriofenone, and although more effects were noted with increasing duration of exposure, effects were generally not severe. These effects included increased liver weight, microscopic changes, and clinical chemistry changes in rats, mice, and/or dogs. Kidney effects included increased organ weight, microscopic changes, and clinical chemistry changes in rats and mice and an increased incidence of chronic nephropathy in rats. Clinical signs included vomiting and loose stools in dogs and peri-genital staining in mice. Also noted were skin changes in the 2-year rat study (atrophy of hair follicles or perifolliculitis) and increased cecal weight or distended cecum in rat studies. Mutagenicity and carcinogenicity testing was negative and the cancer classification for pyriofenone is ''not likely to be carcinogenic to humans'' and therefore there is no cancer risk associated with exposure to pyriofenone.

No developmental or reproductive toxicity occurred in the rat studies. Abortions were noted in the rabbit developmental study and were associated with decreased maternal body weight gain and food consumption. There was no evidence of neurotoxicity and a developmental neurotoxicity study is not needed for pyriofenone. Immunotoxicity testing in rats and mice was negative. Pyriofenone has a low acute toxicity by the oral exposure route. Dermal toxicity, inhalation toxicity, and ocular irritation studies are not available because these exposure routes are not applicable to non-domestic uses. Specific information on the studies received and the nature of the adverse effects caused by pyriofenone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Pyriofenone. Human-Health Risk Assessment for the Establishment of Tolerances for Pyriofenone Fungicide in/on Imported Grapes,'' dated November 1, 2011 at pp. 16–30 in docket ID number EPA–HQ–OPP–2010–0659.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for used for human risk assessment is shown in the Table of this unit.

In risk assessments for import commodities, endpoints are typically selected for dietary exposure only. Endpoints for incidental oral, dermal, and inhalation exposures are not

selected for import tolerances due to lack of potential occupational or residential exposure. No adverse effects attributable to a single exposure were identified for pyriofenone; therefore, an acute dietary endpoint was not selected for pyriofenone.

Consideration was given to selecting abortions/premature delivery from the rabbit developmental study as an endpoint for assessing acute dietary risk. Typically, abortions observed early in the pregnancy in a developmental toxicity study are assumed to be attributable to a single exposure and thus appropriate for acute dietary risk assessment.

In the rabbit developmental toxicity study, abortions occurred in 2 does on gestation day 18 at the highest dose tested (300 milligram/kilogram/day (mg/kg/day). In this case the abortions were determined not to be attributable to a single exposure since the abortions occurred late in gestation (GD 18) and prior to which both does had significantly lower-food consumption resulting in lower body weight or body weight gain. In the range-finding study, abortions and premature delivery seen in 2 does also showed an association to the lower body weight and food consumption. Thus, the potential nutrient deficiency and maternal toxicity resulting from loss in body weight and lower food consumption were assumed to result in the abortions/premature delivery rather than the test compound.

For the chronic dietary risk assessment, a NOAEL of 9 mg/kg/day was selected based on the increased incidence of chronic nephropathy seen in female rats at 46 mg/kg/day (LOAEL) in the 2-year carcinogenicity study. Typically, chronic nephropathy occurs as spontaneous lesions in geriatric rats and in some cases, exposure to a chemical may exacerbate this kidney lesion. In this case, however, chronic nephropathy was considered to be adverse because the incidences of this lesion was significantly increased in females at 46 mg/kg/day (30/35) and also at the next higher dose of 254 mg/kg/day (36/45, $p<0.005$). In the chronic study with dogs, the effects (e.g., clinical signs, alterations in clinical pathology, organ weights, or histopathology) were determined to be not adverse since the findings were isolated, highly variable, and/or there was a lack of dose-response or a clear target organ for toxicity.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRIOFENONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary	An acute dietary endpoint was not selected because toxicity from a single dose was not identified in the hazard database.		
Chronic dietary (All populations).	NOAEL= 9 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.09 mg/kg/day cPAD = 0.09 mg/kg/day	Chronic toxicity/carcinogenicity study—rat NOAEL = 9 mg/kg/day based on increased nephropathy seen in female rats at LOAEL = 46 mg/kg/day.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans''.		

FQPA SF = FQPA Safety Factor. LOAEL = lowest observed adverse effect level.
LOC = Level of Concern. mg/kg/day = milligram/kilogram/day. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies).

Specific information on the toxicological endpoints for pyriofenone can be found at *http://www.regulations.gov* in document ''Pyriofenone. Human-Health Risk Assessment for the Establishment of Tolerances for Pyriofenone Fungicide in/on Imported Grapes,'' dated November 1, 2011 at pp.16–30 in docket ID number EPA–HQ–OPP–2010–0659.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyriofenone, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pyriofenone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for pyriofenone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA conducted an unrefined, screening-level chronic dietary risk assessment assuming tolerance level residues for grapes, raisins, and all other processed grape commodities; and 100% of all grapes are treated with pyriofenone.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyriofenone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue information in the dietary assessment for pyriofenone. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Pyriofenone is not registered for use in the United States; therefore, exposure to pyriofenone in drinking water is not expected.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyriofenone is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether

to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found pyriofenone to share a common mechanism of toxicity with any other substances, and pyriofenone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance assessment action, therefore, EPA has not assumed that pyriofenone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicological database for pyriofenone is complete with regard to pre- and postnatal toxicity, and there are no residual uncertainties. As the data summarized in Unit III.A. showed, pyriofenone exposure did not result in quantitative or qualitative increased sensitivity in the young.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for pyriofenone is complete.

ii. There is no indication that pyriofenone is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that pyriofenone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment was performed based on the assumptions of 100 PCT and tolerance-level residues. This assessment will not underestimate the exposure and risks posed by pyriofenone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists. For this action there is potential exposure to pyriofenone from food only.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, pyriofenone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyriofenone from food only will utilize 1% of the cPAD for children (1–2 years old), the population group receiving the greatest exposure. There are no residential uses for pyriofenone. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyriofenone is not expected.

3. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyriofenone is classified as ''not likely to be carcinogenic to humans.'' EPA does not expect pyriofenone to pose a cancer risk.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyriofenone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method based on the proposed enforcement method (Method ISK 0341/074208, Revision #4) was used to determine residues of pyriofenone in or on grapes (Raw Agricultural Commodity (RAC)) and its processed fractions for the crop field trial and grape processing studies associated with this petition. The validated limit of quantitation (LOQ) is 0.01 ppm. This method was adequately validated for data collection purposes and a successful independent laboratory validation study was conducted. Therefore, the LC/MS/MS method is acceptable for use as an enforcement method.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level MRL.

The Codex has not established a MRL for pyriofenone. However, review of this tolerance on imported grapes is being conducted with Canada, and the U.S. and Canada are harmonized on the residue definition and recommended tolerances.

C. Revisions to Petitioned-For Tolerances

The tolerance level for grape being established by EPA differs from that

proposed in the tolerance petition submitted by the ISK Biosciences Corporation. The Agency used the Organization for Economic Cooperation and Development tolerance calculation procedures to determine that the tolerance level of 0.30 ppm is needed. The petitioner did not propose a separate tolerance for grape, raisin, but processing studies showed that residues could concentrate, necessitating a higher tolerance of 0.50 ppm. Finally, EPA has revised the tolerance expression to clarify that:

1. As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pyriofenone not specifically mentioned.

2. Compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established (without U.S. registrations) for residues of the fungicide, pyriofenone, including its metabolites and degradates, in or on grape at 0.30 ppm and grape, raisin at 0.50 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.660 is added to subpart C to read as follows:

§ 180.660 Pyriofenone; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide pyriofenone, including its metabolites and degradates, in or on the following commodities listed in the table. Compliance with the tolerance levels specified in the table is to be determined by measuring only pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, in or on the following commodities:

Commodity	Parts per million
Grape [1]	0.30
Grape, raisin [1]	0.50

[1] There are no U.S. registrations for grape and grape, raisin.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012–5271 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2011–0108; FRL–9339–8]

RIN 2070–AB27

Modification of Significant New Uses of Tris Carbamoyl Triazine; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of February 8, 2012 concerning the modification of significant new uses of the chemical substance identified generically as tris carbamoyl triazine, which was the subject of premanufacture notice (PMN)

P–95–1098. This document is being issued to correct a typographical error.

DATES: This final rule is effective March 9, 2012.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2011–0108. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Tracey Klosterman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–2209; email address: *klosterman.tracey@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA–Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What does this technical correction do?

When modifying the significant new uses for tris carbamoyl triazine, EPA inadvertently included in § 721.9719 (a)(2)(ii), a cross reference to paragraph (g)(1)(ix) in § 721.72, which requires warnings for developmental effects. EPA did not intend to include this requirement when modifying the significant new uses for tris carbamoyl triazine and did not identify potential concerns for developmental effects in the proposed rule or final rule. This document corrects that typographical error.

The regulatory text for FR Doc. 2012–2909 published in the **Federal Register** of February 8, 2012 (77 FR 6476)(FRL–9330–6) is corrected as follows:

§ 721.9719 [Corrected]

On page 6479, second column, in paragraph (a)(2)(ii), line 5, remove ''(g)(1)(ix),''.

III. Why is this correction issued as a final rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical correction final without prior proposal and opportunity for comment, because notice and comment are unnecessary. The hazard communication requirement that is being removed was never intended to be included in the significant new use rule (SNUR), the PMN submitter who brought the error to EPA's attention is familiar with the issue, and EPA is not aware of and does not expect there to be persons who would be adversely affected by the change as there are no companies making plans based on erroneous notice and no harm resulting from deleting the unnecessary requirement for a developmental effect warning. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

IV. Do any of the Statutory and Executive Order Reviews apply to this action?

This action corrects an error in the final rule published in the **Federal Register** of February 8, 2012, modifying significant new uses of tris carbamoyl triazine; it does not otherwise amend or impose any other requirements. This action is not a ''significant regulatory action'' under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Further, this action does not impose new or change any information collection burden that requires additional review by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The information collection activities contained in the regulations are already approved under OMB control numbers 2070–0012. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and on corresponding collection instruments, as applicable.

On February 18, 2012, EPA certified pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true: (1) A significant number of significant new use notices (SNUNs) would not be submitted by small entities in response to the SNUR, and (2) the SNUN submitted by any small entity would not cost significantly more than $8,300. A copy of that certification is available in the docket for this rule.

This action is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in the final modified SNUR and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true: (1) A significant number of SNUNs would not be submitted by small entities in response to the SNUR and (2) submission of the SNUN would not cost any small entity significantly more than $8,300. Therefore, this technical correction would not have a significant economic impact on a substantial number of small entities.

State, local, and tribal governments were not expected to be affected by the February 8, 2012 final rule (see Unit IX.D. through Unit IX.F. of the preamble to that action), and, similarly, this action is not expected to affect these governments. Accordingly, pursuant to Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538), EPA has determined that this action is not subject to the requirements in UMRA sections 202 and 205 because

it does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector in any 1 year. In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in UMRA sections 203 and 204. For the same reasons, EPA has determined that this action does not have ''federalism implications'' as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999), because it would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the order. Thus, Executive Order 13132 does not apply to this action. Nor does it have ''tribal implications'' as specified in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 22951, November 9, 2000). Thus, Executive Order 13175 does not apply to this action.

Since this action is not economically significant under Executive Order 12866, it is not subject to Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) and Executive Order 13211, entitled Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001). In addition, EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks, which is not the case in this action.

This action does not involve technical standards that would require the consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272).

This action does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, this action does not involve special consideration of environmental justice related issues as specified in Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 24, 2012.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2012–5392 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

46 CFR Parts 530 and 531

[Docket No. 11–17]

RIN 3072–AC47

Certainty of Terms of Service Contracts and NVOCC Service Arrangements

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission amends its rules regarding certainty of terms of service contracts and non-vessel-operating common carrier service arrangements. The rule provides common carriers and shippers with certainty and flexibility by facilitating their use of long-term contracts that adjust based upon an index reflecting changes in market conditions.

DATES: The Final Rule is effective March 7, 2012.

FOR FURTHER INFORMATION CONTACT: Karen V. Gregory, Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001, Phone: (202) 523–5725.

SUPPLEMENTARY INFORMATION:

Background

By Notice of Proposed Rulemaking (NPR) published on October 13, 2011, 76 FR 63581, the Federal Maritime Commission (FMC or Commission) proposed to amend its rules for terms of service contracts and Non-Vessel-Operating Common Carrier service arrangements (NSA). The NPR was intended to remove uncertainty in the use of freight rate or other indices in service contracts and NSAs, while also assisting common carriers and shippers in pursuing stability and flexibility through long-term contracts.

The Commission found that an increasing number of service contracts filed with the Commission reference indices. The ocean freight rates in those service contracts adjust in increments based upon the changes in the referenced index levels or their annual or quarterly averages. The Commission believes that this trend has started to appear because carriers and shippers in the ocean transportation industry are seeking stability through long-term contracts, while trying to preserve flexibility to adjust contract rates reflecting changes in market conditions.

The Commission's current regulation with respect to terms of service contracts and NSAs require that the terms, if they are not explicitly contained in the contracts, must be ''contained in a publication widely available to the public and well known within the industry.'' 46 CFR 530.8(c)(2), 531.6(c)(2). The Commission has received inquiries from the industry as to whether certain freight rate indices meet the Commission's requirement. For example, until August 2011, the Transpacific Stabilization Agreement (TSA) index was not available to the public, even though some service contracts referenced the TSA index before its publication. In addition, although many index publishers' current index levels are available to the public mostly without charge, access to their historical data often requires payment of subscription fees that can reach up to several thousand dollars per year.

While the Commission began to consider whether the service contracts referencing indices comport with its regulation, the Commission also sought to revise its regulations so that they are not unnecessarily burdensome and do not impede innovation and flexibility in commercial arrangements between common carriers and shippers.

The final rule would facilitate references to indices in service contracts and NSAs so that contracting parties can pursue long-term contracts with rates that adjust through an agreed and ascertainable manner.

Comments

The Commission received five public comments responding to the NPR. The comments were submitted by TSA, Westbound Transpacific Stabilization Agreement (WTSA), World Shipping Counsel (WSC), carrier parties to the World Liner Data Agreement (WLDA), and TSC Container Freight (TSC).[1] TSA, WTSA, WSC, and TSC support the Commission's proposed change. Although not explicitly stated, WLDA does not oppose the proposed change.

TSA and WTSA support ''the Commission's effort to expand flexibility in service contracting and welcome[s] the Commission's support of the option to use rate indices.'' TSA and WTSA believe that the ability to reference a price index in service contracts will not only enable the parties to a service contract to allocate risks, but also relieve the parties of the administrative burden of preparing and filing numerous contract amendments in response to changes in market conditions. Eliminating contentious negotiations over numerous contract amendments may help improve relations between shippers and carriers. TSA and WTSA stated that the Commission's rule change ''may also contribute to greater stability and predictability in ocean freight rates, a benefit consistently sought by carriers and shippers alike,'' and welcome and applaud the Commission's clarification of its regulations for service contracts and NSAs. Stating that the parties should be able to refer to the index of their choosing, TSA and WTSA indicated that the Commission's regulation should promote maximum flexibility, including by not favoring or promoting any particular index.

Responding to the Commission's request for comments on the means to ensure that the referenced indices are readily available to the Commission, TSA and WTSA recommend that the Commission require such indices to be made available to the Commission by the carrier party to the contract within thirty (30) days of a written request by the Commission. TSA and WTSA stated that such a requirement, which is based on the Commission's existing requirement at 46 CFR 530.15,[2] would provide the Commission with adequate assurance that it would have access to such indices.

Finally, with respect to the Commission's concerns about how to reduce any impediments to small shippers having the option of index-linked contracts, TSA and WTSA stated that they are not aware of any impediments to a small shipper using such an index in a service contract with a carrier, although their experience with such index-linked contracts is still relatively limited.

WSC supports the proposed changes. WSC stated that the change will facilitate flexibility and freedom of contract by carriers and shippers. Regarding the Commission's question about how to ensure that the information referenced in service contracts is readily available to the Commission, WSC suggests that the Commission require in the regulations that either the carrier or the shipper provide the rate index information upon request by the Commission.

WLDA has contracted with Container Trade Statistics Ltd. (CTS) to aggregate and publish certain data, and through CTS publishes a price index for containerized dry and reefer cargo. WLDA argues that the Commission's NPR created a misperception by identifying four freight rate indices by name, but not the CTS index. WLDA submitted its comments to correct a possible misperception that it would not be lawful to use the CTS index in service contracts, or that the CTS index or other data published by CTS are somewhat less reliable or valuable than the named indices. WLDA asks that the Commission include in the supplementary information of the final rule a statement that the CTS rate index is compliant with the revised regulation.

TSC supports index linked contracts because they will ''provide more contracting options for shippers large and small.''

Discussion

Contrary to WLDA's comments, the NPR named four indices only as examples of freight indices referenced in service contracts that had been submitted to the Commission at the time of the publication of the NPR. The Commission, however, did not intend to imply that those were the only freight indices or that it had any concerns regarding the CTS index. The proposed change was to facilitate, not to limit or impede, long-term contracts between shippers and carriers, while ensuring their compliance with the Shipping Act. As long as the referenced terms comply with the revised regulations, the shippers and carriers are free to use not only any freight indices, but also other indices such as the Bureau of Labor Statistics's Consumer Price Index that was already referred to in certain service contracts.

With respect to the question about possible methods to ensure that the information referred to in service contracts is readily available to the Commission, the Commission adopts TSA's and WTSA's suggestions. As some index publishers require annual payment of up to several thousand dollars for historical data, requiring small shippers to provide that data to the Commission may impede their utilization of long-term contracts. Further, many small shippers may enter into a service contract only once a year, whereas common carriers may enter into service contracts with numerous shippers. Requiring those small shippers to provide the historical data appears to be not only prohibitive, but also unfair because the substantial annual subscription fee may disproportionately negate the benefit of long-term contracts with respect to those small shippers. Therefore, the Commission adopts TSA's and WTSA's recommendations that associated records of such indices, including any historical data used to adjust contract rates, must be made available to the Commission by the carrier party to the contract within thirty (30) days of a written request by the Commission.

TSA and WTSA stated that they are not aware of any impediment to a small shipper using a freight index in a service contract with a carrier who is willing to do so. By requiring carrier parties to service contracts to provide the ''associated records,'' the final rule will further minimize possible impediments to small shippers in entering into long-term contracts.

Finally, as already proposed in the NPR, this final rule also makes the same change to the rule for NSAs, which are NVOCCs' contracts with their shippers and analogous to ocean common carriers' service contracts with their shippers.

Regulatory Findings

The Regulatory Flexibility Act (RFA) allows the head of an agency after a threshold analysis, in lieu of preparing an analysis required by 5 U.S.C. 603 and 604, to certify that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). Such certification may be published in the **Federal Register** either at the time of publication of notice of proposed rulemaking or at the time of publication of the final rule. *Id.*

[1] The Commission determined to accept TSC's late-filed comment.

[2] Section 530.15(c) of the Commission's regulation provides that every carrier or agreement shall, upon written request of the FMC's Director, Bureau of Enforcement, any Area Representative or the Director, Bureau of Economics and Agreements Analysis [now BTA], submit copies of requested original service contracts or their associated records within thirty (30) days of the date of the request.

This Final Rule is intended to enhance the flexibility of regulated entities concluding contractual relationships subject to the Shipping Act and the Commission's regulations. There are two types of regulated entities that this Final Rule may affect: vessel-operating common carriers (VOCCs) and non-vessel-operating common carriers (NVOCCs). The Commission currently has on file registrations (Form FMC–1) for 294 VOCCs. VOCCs are generally not small entities, as defined by North American Industry Classification System's size standards identified by Small Business Administration. 13 CFR 121.201. While some are large, multi-national corporations, most NVOCCs licensed by the Commission have fewer than 500 employees and are therefore small entities. There are currently 4,652 NVOCCs licensed by or registered with the Commission.

The Commission believes that there are approximately 46,962 effective service contracts on file with the Commission between May 1, 2011 through February 9, 2012. Of those, the Commission has identified 62 service contracts referencing indices, approximately 0.13% of the total, that would become subject to the Final Rule. Complying with the Final Rule with respect to 0.13% of the total service contracts would not appear to result in a ''significant economic impact'' on VOCCs. Specifically, only VOCCs whose service contracts refer to indices will be subject to the requirements of 46 CFR 530.8(c)(3) of the Final Rule, and based upon the number of contracts currently on file with the Commission, that number is very small.

Nor will this Final Rule have a ''significant economic impact'' on NVOCCs. The rule simply provides parties to service contracts and NSAs more freedom and flexibility in their commercial arrangements and will not adversely affect small NVOCCs. Unlike VOCC service contracts, there are no NSAs currently on file with the Commission that reference indices, and, therefore, no NSAs would be impacted by the Final Rule.

In view of the above, the Chairman of the Commission hereby certifies, pursuant to 46 U.S.C. 605(b) of the Regulatory Flexibility Act that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

This rule is not a ''major rule'' under 5 U.S.C. 804(2).

As VOCC parties to service contracts and NVOCC parties to NSAs are already required to provide ''associated records'' to the Commission pursuant to the Commission's regulations at 46 CFR 530.15(c) and 531.12(b), this Final Rule does not impose any new recordkeeping or reporting requirements on VOCCs or NVOCCs that would be ''collection of information'' requiring approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 46 CFR Parts 530 and 531

Freight, Maritime carriers, Reporting and recordkeeping requirements.

For the reasons stated in the supplementary information, the Federal Maritime Commission amends 46 CFR parts 530 and 531 as follows.

PART 530—SERVICE CONTRACTS

■ 1. The authority citation for part 530 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40301–40306, 40501–40503, 41307.

■ 2. Revise § 530.8(c) to read as follows:

§ 530.8 Service Contracts.

* * * * *

(c) *Certainty of terms.* The terms described in paragraph (b) of this section may not:

(1) Be uncertain, vague or ambiguous; or

(2) Make reference to terms not explicitly contained in the service contract itself unless those terms are readily available to the parties and the Commission.

(3) Pursuant to § 530.15(c), the carrier party to the service contract must, upon written request by the Commission, provide the Commission with the associated records of the referenced terms. For the purpose of paragraph (c)(2) of this section, the referenced terms will be deemed readily available to the Commission if the carrier party to the service contract provides the Commission with the associated records of the terms within thirty (30) days of the Commission's written request.

* * * * *

PART 531—NVOCC SERVICE ARRANGEMENTS

■ 3. The authority citation for Part 531 continues to read as follows:

Authority: 46 U.S.C. 40103.

■ 4. Revise § 531.6(c) to read as follows:

§ 531.6 NVOCC Service Arrangements.

* * * * *

(c) *Certainty of terms.* The terms described in paragraph (b) of this section may not:

(1) Be uncertain, vague or ambiguous; or

(2) Make reference to terms not explicitly contained in the NSA itself unless those terms are readily available to the parties and the Commission. Reference may not be made to a tariff of a common carrier other than the NVOCC acting as carrier party to the NSA.

(3) Pursuant to § 531.12(b), the carrier party to the NSA must, upon written request by the Commission, provide the Commission with the associated records of the referenced terms. For the purpose of paragraph (c)(2) of this section, the referenced terms will be deemed readily available to the Commission if the carrier party to the NSA provides the Commission with the associated records of the terms within thirty (30) days of the Commission's written request.

* * * * *

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2012–5461 Filed 3–6–12; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 101126522–0640–2]

RIN 0648–XB062

Pacific Cod by Catcher Vessels Less Than 50 Feet (15.2 Meters) Length Overall Using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels (CVs) less than 50 feet (15.2 meters (m)) in length overall (LOA) using hook-and-line gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2012 Pacific cod total allowable catch apportioned to CVs less than 50 feet (15.2 m) LOA using hook-and-line gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 4, 2012, through 1200 hrs, A.l.t., September 1, 2012.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the

GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The A season allowance of the 2012 Pacific cod total allowable catch (TAC) apportioned to CVs less than 50 feet (15.2 m) LOA using hook-and-line gear in the Central Regulatory Area of the GOA is 3,938 metric tons (mt), as established by the final 2011 and 2012 harvest specifications for groundfish of the GOA (76 FR 11111, March 1, 2011), revision to the final 2012 harvest specifications for Pacific cod (76 FR 81860, December 29, 2011), and inseason adjustment to the final 2012 harvest specifications for Pacific cod (77 FR 438, January 5, 2012).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the A season allowance of the 2012 Pacific cod TAC apportioned to CVs less than 50 feet (15.2 m) LOA using hook-and-line gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,903 mt, and is setting aside the remaining 35 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by CVs less than 50 feet (15.2 m) LOA using hook-and-line gear in the Central Regulatory Area of the GOA. After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Acting Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by CVs less than 50 feet (15.2 m) LOA using hook-and-line gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 1, 2012.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 2, 2012.

Steven Thur,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2012–5552 Filed 3–2–12; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 45
Wednesday, March 7, 2012

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 381 and 500

[Docket No. FSIS–2012–0016]

National Advisory Committee on Meat and Poultry Inspection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of committee meeting.

The Food Safety and Inspection Service (FSIS) is announcing, pursuant to the Federal Advisory Committee Act, that the National Advisory Committee on Meat and Poultry Inspection (NACMPI) will hold a public meeting on Wednesday, March 21, 2012, to discuss the proposed rule on the Modernization of Poultry Slaughter Inspection published January 27, 2012. FSIS will provide an overview of the proposed rule, followed by open discussion and comments.

DATES: The Committee will hold a public meeting via Web conference on Wednesday, March 21, 2012, from 1:30 p.m. to 3:30 p.m. E.S.T.

ADDRESSES: The March 21, 2012, meeting will be held via Web conference. Information on accessing the Web conference will be posted on the FSIS Web site at *http://www.fsis.usda.gov/News/Meetings_&_Events/.* The meeting site will also be posted on the FSIS Web site above.

FSIS will finalize the agenda on or before the meeting and post it on the NACMPI Web site, *http://www.fsis.usda.gov/about_fsis/nacmpi/index.asp.*

All interested parties are welcome to attend the meeting and to submit written comments concerning the issue the Committee will discuss. FSIS welcomes comments through April 23, 2012, on this meeting. Comments may be submitted by any of the following methods:

Electronic mail: NACMPI@fsis.usda.gov.

Mail, including floppy disks or CD–ROMs: Send to National Advisory Committee on Meat and Poultry Inspection, USDA, FSIS, 14th & Independence Avenue SW., Room 1180–S, South Building, Washington, DC 20250.

Hand- or courier-delivered items: Deliver to Sally Fernandez at 14th & Independence Avenue SW., Room 1180–S, Washington, DC. To deliver these items, the building security guard must first call (202) 720–9113.

Facsimile: Send to Sally Fernandez, (202) 690–6519. All submissions received must include the Agency name and docket number FSIS–2012–0016.

FOR FURTHER INFORMATION CONTACT: Keith Payne for technical information at (202) 690–6522, or email *keith.payne@fsis.usda.gov,* and Sally Fernandez for meeting information at (202) 690–6524, Fax (202) 690–6519, or email *sally.fernandez@fsis.usda.gov.* Persons requiring a sign language interpreter or other special accommodations should notify Sally Fernandez at the numbers above or by email.

SUPPLEMENTARY INFORMATION: FSIS is announcing, pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the NACMPI will hold a public meeting on Wednesday, March 21, 2012, to discuss the proposed rule on the Modernization of Poultry Slaughter Inspection published January 27, 2012 (77 FR 4408).

Background

The NACMPI provides advice and recommendations to the Secretary of Agriculture pertaining to the Federal and State meat and poultry inspection programs, pursuant to sections 7(c), 24, 205, 301(a)(3), 301(a)(4), and 301(c) of the Federal Meat Inspection Act (21 U.S.C. 607(c), 624, 645, 661(a)(3), 661(a)(4), and 661(c)) and sections 5(a)(3), 5(a)(4), 5(c), 8(b), and 11(e) of the Poultry Products Inspection Act (21 U.S.C. 454(a)(3), 454(a)(4), 454(c), 457(b), and 460(e)).

The Administrator of FSIS is the chairperson of the Committee. Membership of the Committee is drawn from representatives of consumer groups; producers, processors, and marketers from the meat, poultry and egg product industries; State and local government officials; and academia. The current members of the NACMPI are: Patricia K. Buck, Center for Foodborne Illness Research and Prevention; Dr. Fur-Chi Chen, Tennessee State University; Brian R. Covington, Keystone Foods LLC; Dr. Catherine N. Cutter, Pennsylvania State University; Nancy J. Donley, STOP Foodborne Illness; Veneranda Gapud, Fieldale Farms Corporation; Dr. Craig Henry, Deloitte & Touche LLP; Dr. Cheryl D. Jones, Morehouse School of Medicine; Dr. Heidi Kassenborg, Minnesota Department of Agriculture; Sarah A. Klein, Center for Science in the Public Interest; Dr. Shelton E. Murinda, California State Polytechnic University; Dr. Edna Negrón, University of Puerto Rico; Robert G. Reinhard, Sara Lee Corporation; Dr. Craig E. Shultz, Pennsylvania Department of Agriculture; Stanley A. Stromberg, Oklahoma Department of Agriculture, Food, and Forestry; Dr. John D. Tilden, Michigan Department of Agriculture and Rural Development; Carol L. Tucker-Foreman, Consumer Federation of America; Steve E. Warshawer, Mesa Top Farm; Dr. J. Byron Williams, Mississippi State University; and Leonard W. Winchester, Public Health—Seattle & King County.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.*

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at

http://www.fsis.usda.gov/News_&_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Done at Washington, DC, on March 5, 2012.

Alfred V. Almanza,

Administrator.

[FR Doc. 2012–5656 Filed 3–5–12; 4:15 pm]

BILLING CODE 3410–DM–P

FEDERAL RESERVE SYSTEM

12 CFR Part 252

[Regulation YY; Docket No. 1438]

RIN 7100–AD–86

Enhanced Prudential Standards and Early Remediation Requirements for Covered Companies

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Proposed rule; extension of comment period.

SUMMARY: On January 5, 2012, the Board published in the **Federal Register** a notice of proposed rulemaking for public comment to implement the enhanced prudential standards required to be established under section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act or Act) and the early remediation requirements established under section 166 of the Act.

Due to the range and complexity of the issues addressed in the rulemaking, the Board has determined that an extension of the end of the public comment period from March 31, 2012, until April 30, 2012, is appropriate. This action will allow interested persons additional time to analyze the proposed rules and prepare their comments.

DATES: Comments on the proposed rule must be received on or before April 30, 2012.

ADDRESSES: You may submit comments by any of the methods identified in the proposed rule.[1] Please submit your comments using only one method.

FOR FURTHER INFORMATION CONTACT: Molly E. Mahar, Senior Supervisory Financial Analyst, (202) 973–7360, Division of Banking Supervision and Regulation; or Laurie Schaffer, Associate General Counsel, (202) 452–2272, or Dominic A. Labitzky, Senior Attorney, (202) 452–3428, Legal Division.

SUPPLEMENTARY INFORMATION: The proposed rule was published in the **Federal Register** on January 5, 2012,[2] and would implement the enhanced prudential standards required to be established under section 165 of the Dodd-Frank Act and the early remediation requirements established under section 166 of the Act. The enhanced standards include risk-based capital and leverage requirements, liquidity standards, requirements for overall risk management (including establishing a risk committee), single-counterparty credit limits, stress test requirements, and a debt-to-equity limit for companies that the Financial Stability Oversight Council has determined pose a grave threat to financial stability.

In recognition of the complexities of the issues addressed and the variety of considerations involved with implementation of the proposal, the Board requested that commenters respond to numerous questions. The proposed rule stated that the public comment period would close on March 31, 2012.[3]

The Board has received requests from the public for an extension of the comment period to allow for additional time for comments related to the provisions of the proposed rule.[4] The Board believes that the additional period for comment will facilitate public comment on the provisions of the proposed rule and the questions posed by the Board. Therefore, the Board is extending the comment period for the proposed rule from March 31, 2012 to April 30, 2012.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary under delegated authority, March 2, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012–5522 Filed 3–6–12; 8:45 am]

BILLING CODE 6210–01–P

[1] *See* Enhanced Prudential Standards and Early Remediation Requirements for Covered Companies, 77 FR 594 (Jan. 5, 2012).

[2] *Id.*

[3] *Id.*

[4] *See, e.g.,* Comment letters to the Board from The Clearing House *et al.* (Jan. 25, 2012); and The Geneva Association (Feb. 13, 2013).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2012–N–0170]

Modernizing the Regulation of Clinical Trials and Approaches to Good Clinical Practice; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public hearing to obtain input from interested persons on FDA's scope and direction in modernizing the regulations, policies, and practices that apply to the conduct of clinical trials of FDA-regulated products. Clinical trials are a critical source of evidence to inform medical policy and practice, and effective regulatory oversight is needed to ensure that human subjects are protected and resulting clinical trial data are credible and accurate. FDA is aware of concerns within the clinical trial community that certain regulations and policies applicable to the conduct of clinical trials may result in inefficiencies or increased cost and may not facilitate the use of innovative methods and technological advances to improve clinical trial quality. The Agency is involved in an effort to modernize the regulatory framework that governs clinical trials and approaches to good clinical practice (GCP). The purpose of this hearing is to solicit public input from a broad group of stakeholders on the scope and direction of this effort, including encouraging the use of innovative models that may enhance the effectiveness and efficiency of the clinical trial enterprise.

DATES: *Date and Time:* The public hearing will be held on April 23 and 24, 2012, from 8:30 a.m. to 4:30 p.m.

Individuals who wish to attend or present at the public hearing must register on or before close of business on April 2, 2012. To register for the public hearing, email your registration information to *ClinTrialPublicMt@fda.hhs.gov.* Section IV of this document provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until May 31, 2012.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD 20993–0002.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the corresponding docket number found in brackets in the heading of this document.

Transcripts of the public hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public hearing (see section VII of this document).

A live webcast of this public hearing can be viewed at the following Web address on the days of the public hearing: *http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm.* A video record of the public hearing will be available at the same Web address for 1 year.

FOR FURTHER INFORMATION CONTACT: Jennifer Hymiller, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 6333, Silver Spring, MD 20993–0002, 301–796–2147, FAX: 301–847–3529, *Email: ClinTrialPublicMt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trials that yield reliable data are critical to FDA's mission to ensure that drugs, biologics, and medical devices are safe and effective. The regulations that govern the conduct of clinical trials and the protection of human subjects have been in existence for more than 25 years. In the intervening years, there have been dramatic changes in the clinical trial enterprise, including increased size and complexity of clinical trials, increases in the number of clinical trials performed globally, greater use of contract research organizations (CROs), participation of vulnerable populations, and numerous scientific and technological advances. Given these changes and the evolution of the clinical trial enterprise, FDA is evaluating its regulatory approach to clinical trial oversight to ensure that it meets the regulatory objectives of ensuring human subject protection and the quality and integrity of data supporting regulatory decision-making, without being unnecessarily burdensome or unduly impeding implementation of innovative approaches. FDA has already taken a number of steps to improve and modernize its regulations, policies, and practices to ensure they provide for optimal clinical trial quality, data integrity, human subject protection, and flexibility.

In 2004, FDA introduced the Critical Path Initiative (CPI),[1] intended to transform the way medical products are developed, evaluated, and manufactured. One of the CPI's key areas of focus is modernizing clinical trial sciences to make trials safer and more efficient. As part of this larger initiative, FDA launched two initiatives to specifically address human subject protection, data integrity, and clinical trial quality and efficiency.

In 2006, FDA launched the Human Subject Protection and Bioresearch Monitoring Initiative [2] aimed at modernizing and strengthening FDA's oversight and protection of human subjects and the integrity of data in clinical trials. FDA's Office of Good Clinical Practice in the Office of the Commissioner is leading this effort. FDA also established a Human Subject Protection and Bioresearch Monitoring Council that manages and sets FDA policy on bioresearch monitoring, GCP, and human subject protection.

In 2007, FDA and Duke University formed the Clinical Trials Transformation Initiative (CTTI),[3] a public-private partnership with the goal of improving the quality and efficiency of clinical trials. CTTI has been involved in a range of projects, including projects to identify best practices for monitoring and designing quality into clinical trials, improve serious adverse event reporting to investigators, and gather best practices for premarket safety surveillance.

In 2011, FDA published a **Federal Register** notice requesting comment on the development of a plan for the retrospective review of existing FDA regulations [4] in accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review.'' As part of this plan, FDA is conducting a review of existing regulations to determine which, if any, of its rules are outmoded, ineffective, insufficient or excessively burdensome and may be good candidates to be modified, streamlined, expanded or repealed. The Agency is also evaluating its framework for periodically analyzing existing rules.[5]

Over the past few years, FDA has issued a number of regulations and guidance documents related to clinical trial conduct. The following regulations and guidances are highlighted below to exemplify the direction and scope of FDA's effort to modernize the regulations, policies, and practices that apply to the conduct of clinical trials. The CPI, Human Subject Protection and Bioresearch Monitoring Initiative, and CTTI have helped inform these regulations and guidances:

1. Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies—Final Rule, published September 29, 2010 (75 FR 59935);

2. Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects—Final Guidance, published October 26, 2009 (74 FR 55052);

3. Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring—Draft Guidance, published August 29, 2011 (76 FR 53683);

4. Electronic Source Documentation in Clinical Investigations—Draft Guidance, published January 7, 2011 (76 FR 1173);

5. Adverse Event Reporting to IRBs—Improving Human Subject Protection—Final Guidance, published January 15, 2009 (74 FR 2599);

6. Exception from Informed Consent Requirements for Emergency Research—Final Guidance, published April 4, 2011 (76 FR 18558);

The collaborative effort with CTTI also identified Quality Risk Management (QRM) principles and Quality by Design (QbD) as models that, with adaptations, could contribute to improved data quality and integrity in clinical trials. QRM is a systematic process to identify, assess, control,

[1] For more information on FDA's Critical Path Initiative, see *http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm.*

[2] For more information on FDA's Human Subject Protection and Bioresearch Monitoring Initiative, see *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm226306.htm.*

[3] For more information on the Clinical Trials Transformation Initiative, see *https://www.trialstransformation.org/.*

[4] 76 FR 23520; April 27, 2011.

[5] 76 FR 3821.

communicate, and review the risks associated with a process or activity. QbD, a risk-based, quality approach that has been successful in the manufacturing arena, emphasizes building quality into a process from the beginning. Applied to clinical trials, this approach would prospectively define factors most critical to trial quality and data integrity (e.g., proper randomization, effective blinding to ensure unbiased ascertainment and analysis of study outcomes) and prospectively identify risks critical to those factors. The sponsor would then design the protocol, oversight and monitoring mechanisms, as well as data management, archiving, and analysis processes to eliminate or mitigate those risks.

FDA has also taken steps to improve its clinical trial inspection processes and coordinate inspection processes globally. Ongoing efforts are aimed at developing new approaches for selecting clinical investigator sites for inspection and for improving the warning letter process. FDA is also involved in a Good Clinical Practice Initiative [6] with the European Medicines Agency (EMA), in which FDA and the EMA have shared information on applications, collaborated on joint and observational inspections, participated in bilateral training, and kept each other informed of GCP-related legislation, regulatory guidance, and related documents. These steps have facilitated improvements in FDA's inspection coverage and decision-making processes.

In various forums, FDA has been told that certain regulations and compliance practices may result in inefficiencies or may not facilitate the use of innovative methods to improve clinical trial quality or the use of technological advances (e.g., use of the Internet to gather data, conduct certain types of research, obtain informed consent). FDA has also heard from clinical trial sponsors and CROs that sponsors and CROs are reluctant to change their processes related to clinical trial oversight and management because of uncertainty about whether new processes would be in compliance with applicable regulations. FDA recognizes that it must effectively leverage its available resources and take additional steps to strategically evolve and modernize its regulatory approach to the conduct of clinical trials. FDA is striving to align regulatory processes to meet the needs of its many stakeholders, including those who design and conduct trials, those who participate in trials, and those who depend on the results of those trials to make informed health care decisions.

[6] For more information on the EMA–FDA Good Clinical Practice Initiative, see *http://www.fda.gov/downloads/InternationalPrograms/FDABeyondOurBordersForeignOffices/EuropeanUnion/EuropeanUnion/EuropeanCommission/UCM266259.pdf.*

II. Purpose of Hearing

The purpose of this public hearing is to obtain input from clinical trial sponsors, CROs, clinical investigators, academic institutions, institutional review boards (IRBs), professional societies, trade organizations, patient and consumer groups, and other interested parties on the scope and direction of FDA's future efforts to evolve and modernize its regulatory approach to the conduct and oversight of clinical trials. FDA's primary focus is on good clinical practice, including clinical protocol design to ensure the reliability of data, safety surveillance and reporting, quality control processes (*e.g.,* monitoring and training), quality assurance (e.g., auditing), and any other processes directed at ensuring trial quality, data integrity, or human subject protection. FDA is interested in ways (*e.g.,* workshops, strategic alliances) to foster implementation of innovative methods to ensure human subject protection and data quality and integrity, including risk-based approaches in the design, oversight, and conduct of clinical investigations. FDA is seeking feedback on specific GCP regulations, policies, and practices that may need clarification or revision to facilitate advances in the ways that clinical trials are conducted, remove impediments to the use of innovative approaches, or otherwise improve the conduct of clinical trials. FDA also welcomes comments on additional issues that will help the Agency modernize its oversight and improve the quality and efficiency of clinical trials.

III. Issues for Discussion

In addition to the general information requests in section II of this document, FDA is interested in obtaining information and public comment on the following specific issues.

1. Increasing clinical trial complexity (e.g., participation of vulnerable populations, increased frequency of outsourcing) and globalization are posing challenges for sponsors, clinical investigators, IRBs, patients, and FDA. FDA has been involved in a number of efforts to ensure that the Agency's GCP regulations, policies, and practices are optimal for ensuring clinical trial quality, data integrity, and human subject protection while providing flexibility to conduct trials in the 21st century.

a. What additional efforts should FDA pursue to modernize the Agency's GCP regulations, policies, and practices? For example, are there specific FDA regulations, guidances, or practices (*e.g.,* compliance programs) that should be a high priority for clarification or revision? Are there other steps (*e.g.,* pilot projects, strategic alliances) that would help ensure clinical trial quality and subject safety, provide flexibility, or improve the efficiency of the clinical trial process? For each of the suggested efforts, specifically identify the reasons that the current approach is not optimal, how the suggested effort would ensure clinical trial quality, subject safety, and/or improve the efficiency of the clinical trial process, and what the preferred priority of the efforts should be.

b. What efforts could FDA consider that could help mitigate some of the challenges resulting from increased clinical trial complexity and globalization? For each of the suggested efforts, specifically identify how the effort could help mitigate these challenges.

2. FDA is interested in fostering the use of innovative methods and models, including QRM principles and QbD, as well as the use of technological advances (*e.g.,* use of the Internet to gather data, conduct certain types of research, obtain informed consent). The Agency seeks comments on how the use of innovative methods, models, and technological advances could contribute to data integrity, clinical trial quality, and the safety of human subjects, as well as streamline the conduct of clinical trials.

a. What are some innovative methods or models that facilitate building quality into the conduct of trials (*e.g.,* by identifying, preventing, or minimizing errors that have the potential to compromise human subject safety and data integrity)? FDA requests feedback on experiences with implementing such methods or models (e.g., lessons learned), as well as data supporting the use of any suggested methods or models.

b. FDA recognizes that the clinical trial process involves various stakeholders (e.g., sponsors, CROs, IRBs, investigators, patients) with different roles and responsibilities in ensuring human subject protection and generating valid study data. What are the specific stakeholder challenges presented by FDA's GCP regulations, policies, and/or practices to building quality into the clinical trial process (e.g., for a study that is conducted and overseen by multiple entities)?

c. What are some ways in which FDA could encourage adoption of these

methods and models? For example, how can FDA support effective communication and coordination among all entities involved in the conduct of a trial to ensure a focus on the protection of human subjects and quality across the clinical trial process?

d. How should FDA focus its efforts in GCP regulations, policies, or practices to facilitate the use of technological advances, while maintaining the protection of research participants and the quality and integrity of data supporting regulatory decision-making?

IV. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-serve basis. Individuals who wish to attend the public hearing must register by sending an email to *ClinTrialPublicMt@fda.hhs.gov* on or before April 2, 2012, and provide complete contact information, including: Name, title, affiliation, address, email, and phone number. Those without email access may register by contacting Jennifer Hymiller (see **FOR FURTHER INFORMATION CONTACT**). Because seating is limited, FDA may limit the numbers of participants from each organization. Registrants will receive confirmation once they have been accepted for participation in the hearing. Onsite registration on the day of the hearing will be based on space availability on the day of the event starting at 7:30 a.m. If registration reaches maximum capacity, FDA will post a notice closing the meeting registration for the hearing at *http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm.*

Individuals who wish to present at the public hearing must register on or before April 2, 2012, through the email *ClinTrialPublicMt@fda.hhs.gov,* and state this intention on their notice of participation. You must provide complete contact information, including: Name, title, affiliation, address, email, and phone number. FDA has included questions for comment in section III of this document. You should identify the topic or section and the number of each question you wish to address in your presentation, so that FDA can consider that in organizing the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times, and make available a draft agenda on *http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm* approximately 2 weeks before the public hearing. Once FDA notifies registered presenters of their scheduled times, presenters should submit to electronic copy of their presentation to *ClinTrialPublicMt@fda.hhs.gov* on or before April 16, 2012.

If you need special accommodations because of disability, please contact Jennifer Hymiller (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

A live webcast of this public hearing can be viewed at the following Web address on the days of the public hearing: *http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm.* A video record of the public hearing will be available at the same Web address for 1 year.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VII of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

VI. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

Transcripts of the public hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.regulations.gov* approximately 30 days after the public hearing. A transcript will also be made available in either hard copy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: March 1, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5476 Filed 3–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0043]

RIN 1625—AA00

Safety Zone; Antique Boat Show, Niagara River, Grand Island, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on Niagara River, Grand Island, NY. This proposed rule is intended to restrict vessels from a portion of the Niagara River during the Antique Boat Show powerboat races. The safety zone established by this proposed rule is necessary to protect spectators, participants, and vessels from the hazards associated with powerboat races.

DATES: Comments and related material must be received by the Coast Guard on or before April 6, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0043 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email LT Christopher Mercurio, Chief of Waterway Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9343, email *SectorBuffaloMarineSafety@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0043), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2012–0043'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0043'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register.**

Background and Purpose

Between 10 a.m. and 4 p.m. on Sept. 8, 2012, a series of hydroplane and power boat races will take place on the Niagara River near Grand Island, NY. The Captain of the Port Buffalo has determined that hydroplane racing presents significant hazards to public spectators and participants.

Discussion of Proposed Rule

This proposed temporary safety zone is necessary to ensure the safety of spectators and vessels during the Antique Boat Show.

The proposed safety zone will be effective and enforced from 9:30 a.m. until 4:30 p.m. on September 8, 2012.

The proposed safety zone will encompass all waters of Niagara River, Grand Island, NY starting at position 42°59′59″ N, 078°56′22″ W, East to 49°59′54″ N, 078°56′14″ W, South to 42°57′54″ N, 078°56′04″ W, West to 42°057′48″ N, 078°56′22″ W. (NAD 83)

Entry into, transiting, or anchoring within the proposed safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his on-scene representative. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that those Orders.

It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). We conclude that this proposed rule is not a significant regulatory action

because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this proposed rule will be relatively small and enforced for relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed temporary rule may affect the following entities, some of which might be small entities: the owners of operators of vessels intending to transit or anchor in a portion of the Niagara River near Grand Island, New York between 9:30 a.m. to 4:30 p.m. on September 8, 2012.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: this rule will be in effect for only a few hours and the safety zone will allow vessels to move freely around the safety zone on the Niagara River. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact LT Christopher Mercurio, Chief of Waterway Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9343, email *SectorBuffaloMarineSafety@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. Because it involves the establishment of a safety zone.

An environmental analysis checklist and a preliminary categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR parts 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T09–0043 to read as follows:

§ 165.T09–0043 Safety Zone; Antique Boat Show, Niagara River, Grand Island, NY.

(a) Location. The safety zone will encompass all waters of the Niagara River, Grand Island, NY starting at position 42°59′59″ N, 078°56′22″ W, East to 42°59′54″ N 078°56′14″ W, South to 42°57′54″ N, 078°56′04″ W, West to 42°057′48″ N, 078°56′22″ W. (NAD 83)

(b) Effective and enforcement period. This regulation is effective and will be enforced on September 8, 2012 from 9:30 a.m. until 4:30 p.m.

(c) Regulations. (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf. The on-scene representative of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: February 14, 2012.

S.M. Wischmann,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2012–5497 Filed 3–6–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0095]

RIN 1625–AA00

Safety Zone; Virginia Beach Oceanfront Air Show, Atlantic Ocean, Virginia Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a safety zone on the navigable waters of the Atlantic Ocean in Virginia Beach, VA. This action is necessary to provide for the safety of life on navigable waters during the Virginia Beach Oceanfront Air Show. This action is intended to restrict vessel traffic movement to protect mariners from the hazards associated with air show events.

DATES: Comments and related material must be received by the Coast Guard on or before April 6, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0095 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Christopher O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5581, email *Christopher.A.ONeal@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0095), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at

the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2012–0095'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½; by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0095'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact LCDR Chris O'Neal at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Basis and Purpose

On May 31, 2012 through June 3, 2012, the United States Navy will host an air show event over the Atlantic Ocean in Virginia Beach, VA. In recent years, there have been unfortunate instances of jets and planes crashing during performances at air shows. Along with a jet or plane crash, there is typically a wide area of scattered debris that also damages property and could cause significant injury or death to mariners observing the air shows. Due to the need to protect mariners and the public transiting the Atlantic Ocean immediately below the air show from hazards associated with the air show, a Coast Guard established safety zone bound by the following coordinates will be enforced: 36°-00′-00″ N /075°-58′-12″ W, 36°-51′-36″ N/075°-57′-36″ W, 36°-49′-48″ N/075°-57′-00″ W, 36°-49′48″ N/075°-57′-36″ W (NAD 1983). Access to this area will be temporarily restricted for public safety purposes.

Discussion of Proposed Rule

The Coast Guard proposes establishing a safety zone on specified waters of the Atlantic Ocean bounded by the following coordinates: 36°-00′-00″ N/075°-58′-12″ W, 36°-51′-36″ N/075°-57′-36″ W, 36°-49′-48″ N/075°-57′-00″ W, 36°-49′48″ N/075°-57′-36″ W (NAD 1983), in the vicinity of Virginia Beach, Virginia. This safety zone is proposed in the interest of public safety during the Virginia Beach Oceanfront Air Show and will be enforced from 11 a.m. until 5 p.m. on May 31, 2012, from 11 a.m. until 5 p.m. on June 1, 2012, 11 a.m. until 5 p.m. on June 2, 2012, and from 11 a.m. until 5 p.m. on June 3, 2012. Access to the safety zone will be restricted during the specified date and times. Except for vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the safety zone.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that those Orders.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. Although this proposed regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities because the zone will only be in place for a limited duration and maritime advisories will be issued allowing the mariners to adjust their plans accordingly.

This proposed rule would affect the following entities, some of which might be small entities: The owners and operators of vessels intending to transit or anchor in that portion of the Atlantic Ocean from 11 a.m. until 5 p.m. on May 31, 2012, from 11 a.m. until 5 p.m. on June 1, 2012, 11 a.m. until 5 p.m. on June 2, 2012, and from 11 a.m. until 5 p.m. on June 3, 2012.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it

qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact LCDR Christopher O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5581, email *Christopher.A.Oneal@uscg.mil*. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. In accordance with the Coastal Zone Management Act, National Environmental Policy Act, and the Endanger Species Act an environmental consultation has been initiated with Virginia Department of Environmental Quality, Army Corps of Engineers, Virginia Marine Resource Commission, and the Department of Conservation and Recreation. Upon receipt of consultation comments all documentation will be made available in the docket where indicated under **ADDRESSES**. This proposed rule involves establishing a temporary safety zone. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C., 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T05–0095 to read as follows:

§ 165.T05–0095 Safety Zone; Virginia Beach Oceanfront Air Show, Atlantic Ocean, Virginia Beach, VA.

(a) *Regulated Area.* The following area is a safety zone: Specified waters of the Captain of the Port Sector Hampton Roads zone, as defined in 33 CFR 3.25–

10, in the vicinity of the Atlantic Ocean in Virginia Beach, VA bound by the following coordinates: 36°-00′-00″ N/075°-58′-12″ W, 36°-51′-36″ N/075°-57′-36″ W, 36°-49′-48″ N/075°-57′-00″ W, 36°-49′48″ N/075°-57′-36″ W (NAD 1983), in the vicinity of Virginia Beach, Virginia.

(b) *Definition:* For the purposes of this part, Captain of the Port Representative means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Hampton Roads, Virginia to act on his behalf.

(c) *Regulations:* (1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, Hampton Roads can be reached through the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia at telephone Number (757) 668–5555.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement Period:* This regulation will be enforced from 11 a.m. until 5 p.m. on May 31, 2012, from 11 a.m. until 5 p.m. on June 1, 2012, 11 a.m. until 5 p.m. on June 2, 2012, and from 11 a.m. until 5 p.m. on June 3, 2012.

Dated: February 17, 2012.

Mark S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2012–5543 Filed 3–6–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0076]

RIN 1625–AA00

Safety Zone; Baltimore Air Show, Patapsco River, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone during the ''Baltimore Air Show,'' which consists of aerial practices, performance demonstrations and air shows, to be held over certain waters of the Patapsco River adjacent to the Fort McHenry National Monument and Historic Shrine in Baltimore, Maryland from June 14, 2012 through June 17, 2012. This proposed rule is necessary to provide for the safety of life on navigable waters during the event. This action is intended to temporarily restrict vessel traffic in portions of the Patapsco River during the event.

DATES: Comments and related material must be received by the Coast Guard on or before April 6, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0076 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov*.

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Ronald Houck, Sector Baltimore Waterways Management Division, Coast Guard; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0076), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2012–0076'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0076'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The U.S. Navy History & Heritage Command, Office of Commemorations, is planning to conduct the ''Baltimore Air Show'' on June 15, 2012, June 16, 2012 and June 17, 2012. The public event will consist of military and civilian aircraft performing low-flying, high-speed precision maneuvers and aerial stunts over specified waters of the Patapsco River and navigable channels in Baltimore Harbor. In addition to the air show dates, military and civilian aircraft performing in the air show will conduct practice and demonstration maneuvers and stunts over specified waters of the Patapsco River and navigable channels in Baltimore Harbor on June 14, 2012. A large spectator fleet is anticipated for the event, as part of the War of 1812 Bicentennial Commemoration activities. To provide for the safety of participants, spectators, and transiting vessels, the Coast Guard proposes to temporarily restrict vessel traffic on specified waters of the Patapsco River in the vicinity of the practices, demonstrations and air shows. To address safety concerns during the event, the Captain of the Port, Baltimore proposes to establish a safety zone upon certain waters of the Patapsco River. This proposed zone addresses safety concerns immediately outside the aerobatic show box, including the required patrols of law enforcement and safety vessels, establishment of emergency egress routes, and sponsor-designated spectator areas.

Discussion of Proposed Rule

The Captain of the Port Baltimore is proposing to establish a temporary safety zone for certain waters of the Patapsco River, located adjacent to the Fort McHenry National Monument and Historic Shrine in Baltimore, Maryland. The proposed zone is in the interest of public safety during the Baltimore Air Show. The proposed zone is located south of Locust Point, between Port Covington and Seagirt Marine Terminal, within all waters in the area bounded by a line connecting position latitude 39°16′00″ N, longitude 076°36′30″ W; thence to latitude 39°16′00″ N, longitude 076°33′00″ W; thence to latitude 39°14′30″ N, longitude 076°33′00″ W; thence to latitude 39°14′30″ N, longitude 076°36′30″ W; thence to the point of origin. This safety zone will be enforced from 10 a.m. until 6 p.m. each day from June 14, 2012 through June 17, 2012. Within the proposed safety zone, an aerobatic show box, approximately 12,000 feet long and 3,000 feet wide, is located within an area bounded by a line connecting position latitude 39°15′44″ N, longitude 076°35′55″ W; to latitude 39°15′19″ N, longitude 076°33′25″ W; thence to latitude 39°14′49″ N, longitude 076°33′35″ W; thence to latitude 39°15′15″ N, longitude 076°36′04″ W; thence to point of origin. Access to the safety zone will be restricted during the specified dates and times. Except for vessels authorized by the Captain of the Port or his designated representative, no person or vessel may enter or remain in the safety zone. U.S. Coast Guard vessels will be provided to enforce the safety zone. The Captain of the Port Baltimore will issue Broadcast Notices to Mariners to publicize the safety zone and notify the public of changes in the status of the zone. Such notices will continue until the event is complete.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. Although this safety zone restricts vessel traffic through the affected area, the effect of this regulation will not be significant due to the limited size and duration that the regulated area will be in effect. In addition, notifications will be made to the maritime community via marine information broadcasts so mariners may adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate or transit through or within the safety zone during the enforcement period. The safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The safety zone is of limited size and duration. Maritime advisories will be widely available to the maritime community before the effective period.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Mr. Ronald L. Houck, Coast Guard Sector Baltimore, Waterways Management Division, at telephone number 410–576–2674. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves establishing a temporary safety zone. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add a temporary section, § 165.T05–0076 to read as follows:

§ 165–T05–0076 Safety Zone; Baltimore Air Show, Patapsco River, Baltimore, MD.

(a) *Regulated areas.* The following locations are a regulated area: (1) All waters of the Patapsco River, within an area bounded by a line connecting position latitude 39°16′00″ N, longitude 076°36′30″ W; thence to latitude 39°16′00″ N, longitude 076°33′00″ W; thence to latitude 39°14′30″ N, longitude 076°33′00″ W; thence to latitude 39°14′30″ N, longitude 076°36′30″ W; thence to the point of origin, located adjacent to the Fort McHenry National Monument and Historic Shrine in Baltimore, Maryland.

(2) Within the regulated area described in paragraph (a)(1) of this section, an aerobatic show box is located on all waters of the Patapsco River, within an area bounded by a line connecting position latitude 39°15′44″ N, longitude 076°35′55″ W; to latitude 39°15′19″ N, longitude 076°33′25″ W; thence to latitude 39°14′49″ N, longitude 076°33′35″ W; thence to latitude 39°15′15″ N, longitude 076°36′04″ W; thence to point of origin. All coordinates reference Datum NAD 1983.

(b) *Definitions:* As used in this section: (1) *Captain of the Port Baltimore* means the Commander, U.S. Coast Guard Sector Baltimore, Maryland.

(2) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the safety zone described in paragraph (a) of this section.

(c) *Regulations:* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05.0076. (1) All persons are required to comply with the general regulations governing safety zones found in 33 CFR 165.23.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. All vessels underway within this safety zone at the time it is implemented are to depart the zone.

(3) Persons desiring to transit the area of the safety zone must first request authorization from the Captain of the Port Baltimore or his designated representative. To seek permission to transit the area, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing lights, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore or his designated representative and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(4) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(d) *Enforcement periods:* This section will be enforced from 10 a.m. until 6 p.m. on June 14, 2012, from 10 a.m. until 6 p.m. on June 15, 2012, from 10 a.m. until 6 p.m. on June 16, 2012, and from 10 a.m. until 6 p.m. on June 17, 2012.

Dated: February 23, 2012.

Mark P. O'Malley,

Captain, U.S. Coast Guard, Captain of the Port Baltimore.

[FR Doc. 2012–5547 Filed 3–6–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0114]

RIN 1625–AA00

Safety Zone; Rocketts Red Glare Fireworks, Ancarrows Landing Park, James River, Richmond, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a safety zone on the navigable waters of James River in Richmond, VA in support of the Labor Day Fireworks event. This action is necessary to provide for the safety of life on navigable waters during the Rocketts Red Glare Fireworks show. This action is intended to restrict vessel traffic movement to protect mariners and spectators from the hazards associated with aerial fireworks display.

DATES: Comments and related material must be received by the Coast Guard on or before April 6, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0114 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Christopher O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5581, email *Christopher.A.ONeal@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0114), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2012–0114'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an

unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0114'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact LCDR Christopher O'Neal at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Basis and Purpose

On May 27, 2012, the City of Richmond will sponsor a fireworks display on the shoreline of the navigable waters of the James River. The fireworks will be launched from a shore-based platform centered on position 37°31′13.1″ N/077°25′07.84″ W (NAD 1983). Due to the need to protect mariners and spectators from the hazards associated with the fireworks display, such as the accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris, vessel traffic will be temporarily restricted on all navigable waters within 420 feet of the fireworks launch site.

Discussion of Proposed Rule

The Captain of the Port Hampton Roads proposes establishing a safety zone on specified waters of the James River within the area bounded by a 420-foot radius circle centered on position 37°31′13.1″ N/077°25′07.84″ W (NAD 1983). This safety zone will be established in the vicinity of Richmond, VA from 9 p.m. to 10 p.m. on May 27, 2012. In the interest of public safety, general navigation within the safety zone will be restricted during the specified date and times. Except for participants and vessels authorized by the Coast Guard Captain of the Port or his representative, no person or vessel may enter or remain in the regulated area.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We expect the economic impact of this proposed rule to be so minimal that a full regulatory evaluation is unnecessary. Although this proposed regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities because the zone will only be in place for a limited duration, it is limited in size, and maritime advisories will be issued allowing the mariners to adjust their plans accordingly.

This proposed rule would affect the following entities, some of which might be small entities: the owners and operators of vessels intending to transit or anchor in that portion of the James River from 9 p.m. to 10 p.m. on May 27, 2012.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact LCDR Christopher O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5580, email *Christopher.A.ONeal@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination will be available in the docket where indicated under **ADDRESSES**. This proposed rule involves establishing a safety zone around a fireworks display. The fireworks are launched from land and the safety zone is intended to keep mariners away from any debris that may enter the water. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T05–0114 to read as follows:

§ 165.T05–0114 Safety Zone; Rocketts Red Glare Fireworks, Ancarrows Landing Park, James River, Richmond, VA.

(a) *Regulated Area.* The following area is a safety zone: All waters of the James River in the vicinity of Richmond, VA within 420 feet of position 337°31′13.1″ N/077°25′07.84″ W (NAD 1983).

(b) Definition: For the purposes of this part, Captain of the Port Representative means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Hampton Roads, Virginia to act on his behalf.

(c) Regulations: (1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, Hampton Roads can be reached through the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia at telephone Number (757) 668–5555.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement Period:* This regulation will be enforced from 9 p.m. until 10 p.m. on May 27, 2012.

Dated: February 22, 2012.

Mark S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2012–5549 Filed 3–6–12; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register
Vol. 77, No. 45
Wednesday, March 7, 2012

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agency Information Collection Activities; Proposed Collection; Comment Request—SuperTracker Information Collection for Registration, Login, and Food Intake and Physical Activity Assessment Information

AGENCY: Center for Nutrition Policy and Promotion (CNPP), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on a proposed information collection. This is an extension with revision to a currently approved collection. The SuperTracker is an on-line dietary and physical activity self-assessment tool. The information collected can only be accessed by the user and will not be available to CNPP or any other public agency for purposes of evaluation or identification.

DATES: Written comments on this notice must be submitted on or before May 7, 2012.

ADDRESSES: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Jackie Haven, Director, Nutrition Marketing and Communication Division, Center for Nutrition Policy and Promotion, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1034, Alexandria, Virginia, 22302. You may also download an electronic version of this notice at *http://www.fns.usda.gov/fsp/rules/regulations/default.htm* and comment via email at *SNAPHQ–Web@fns.usda.gov* or use the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Donna Johnson-Bailey, (703) 305–7600.

SUPPLEMENTARY INFORMATION:

Title: SuperTracker Information Collection for Registration, Login and Food Intake and Physical Activity Assessment.

OMB Control Number: 0584–0535.

Expiration Date: July 31, 2012.

Type of Request: Revision of a currently approved collection.

Abstract: SuperTracker is an Internet based diet and physical activity self-assessment tool which allows users to monitor their daily food intakes and physical activity information. Based on 2010 Dietary Guidelines, the SuperTracker delivers nutrition education by allowing users to monitor their intake and explore ways to improve their food and physical activity choices. Motivational education messages are generated and tailored to the user's personal assessment results.

Individuals can use the SuperTracker without registration. However, all users may voluntarily enter and save information by registering with a username and password. The historical and trend data entered allows users to identify areas for improvement and reference short- and long- term changes to diet and physical activity behaviors. SuperTracker includes optional functions that consumers may use at their discretion, including a journaling feature to capture information for a selected category. Consumers may also post system-generated congratulatory and tip messages to Facebook or Twitter using their personal social media account. Through leveraging the user's existing social network, the user is more likely to experience positive feedback and encouragement in achieving their dietary and/or physical activity goals. Social media functionality is provided as a consumer benefit but does not impact consumer results or reports. The previous online tools provided limited functionality and more complex reporting features. The revised SuperTracker offers streamlined navigation features allowing consumers to quickly and easily enter data for one or multiple days. SuperTracker integrates all features and functions found in previous CNPP online diet and physical activity tools into one application within the *ChooseMyPlate.gov* Web site. Hence, all access to the SuperTracker is obtained through the *ChooseMyPlate.gov.*

Affected Public: Individual/Households.

Estimated Number of Respondents: The following total annual burden estimates are based on the data obtained from current web trend tool, Google Analytics from June 2011—January 2012. Revised estimates are based on an increased number of visits to the Web site, the average time per visit and the increased efficiency of the tool that combines all functions from previous online assessment tools into one.

- The number of annual visitors to the Web site is expected to be about 11.2 million and they will spend approximately 5 minutes one time only.
- Approximately 30% of annual visitors will complete a one-time registration, log-in and assessment for the revised online assessment tool. This information is based on data from the previous most frequently used online tool (rounded up = 3.3 million).
- The average number of weekly visitors is approximately 200,000.
- 30% of the weekly visitors return each week to complete tracking activities (approximately 60,000).

Estimated Time per Response: For the SuperTracker, it will take individuals approximately 1 minute (.0167) to initially register for a system logon ID and password. It typically takes users 30 seconds (.0083) to routinely login to the system and approximately 15 minutes (.25) to complete food and physical activity data entry log for 1 day. Based on Google Analytics, repeat users will enter data on average 3 times per week. The amount of time spent completing

entry and using expanded functionality is estimated at 45 minutes per week.

REPORTING BURDEN

Affected public	Description of activity	(b) Form No.	(c) Number annual respondents	(d) Annual frequency of responses per respondent	(e) Estimated total annual responses (c × d)	(f) Hours per response	(g) Total annual burden (e × f)
Individual and Households.	Annual Website Visitors	.....	11,200,000	1	11,200,000	0.05	560,000
	One time SuperTracker Registration.	N/A	3,300,000	1	3,300,000	0.0167	55,110
	One time SuperTracker Log-in ..	N/A	3,300,000	1	3,300,000	0.0083	27,390
	Food/Physical Activity Data Entry for 1 Week.	N/A	3,300,000	1	3,300,000	0.25	825,000
	Repeat Log-ins for 1 Year	N/A	60,000	51	3,060,000	0.0083	25,398
	Repeat Food/Physical Activity Data Entries for 1 Year.	N/A	60,000	51	3,060,000	0.75	2,295,000
Total Annual Burden Estimated.	.....	.....	11,200,000	.....	27,220,000	.....	3,787,898

Dated: March 1, 2012.

Rajen Anand,

Executive Director, Center for Nutrition Policy and Promotion.

[FR Doc. 2012–5440 Filed 3–6–12; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Funding for the Conservation Loan Program; Farm Loan Programs

AGENCY: Farm Service Agency, USDA.

ACTION: Notice.

SUMMARY: This notice announces that the Farm Service Agency (FSA) now has funding for and is accepting guaranteed loan applications for the Conservation Loan (CL) Program. Due to a lack of program funding for direct CLs, direct loan applications are not being accepted at this time.

FOR FURTHER INFORMATION CONTACT: Connie Holman; telephone: (202) 690–0756. Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION: On May 13, 2011, FSA published a notice in the **Federal Register** (76 FR 27986) announcing that FSA was no longer accepting direct or guaranteed loan applications for the CL Program because of a lack of funding.

On November 18, 2011, FSA received an appropriation to fund guaranteed CLs under the Consolidated and Further Continuing Appropriations Act, 2012 (Pub. L. 112–55). Therefore, FSA has resumed accepting guaranteed loan applications for the CL Program.

FSA is not accepting direct CL applications as no new funding has been appropriated at this time. Conservation projects may still be funded through FSA's direct Farm Ownership and Farm Loan Operating programs for eligible applicants who do not qualify for the Guaranteed CL Program.

Potential guaranteed loan applicants should contact a lender. Potential direct loan applicants should contact their FSA state or county office; office locations can be found at *http://www.fsa.usda.gov.*

Signed on March 1, 2012.

Bruce Nelson,

Administrator, Farm Service Agency.

[FR Doc. 2012–5529 Filed 3–6–12; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), the Rural Utilities Service (RUS) invites comments on this information collection for which RUS intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by May 7, 2012.

FOR FURTHER INFORMATION CONTACT: Michele L. Brooks, Director, Program Development and Regulatory Analysis, Rural Utilities Service, 1400 Independence Ave. SW., STOP 1522, Room 5818, South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078; Fax: (202) 720–8435.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies an information collection that RUS is submitting to OMB for extension.

Comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic,

mechanical or other technological collection techniques or other forms of information technology. Comments may be sent to Michele L. Brooks, Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, STOP 1522, 1400 Independence Ave. SW., Washington, DC 20250–1522. Fax: (202) 720–8435.

Title: Advance of Loan Funds and Budgetary Control and Other Related Burdens.

OMB Control Number: 0572–0015.

Type of Request: Extension of a currently approved collection.

Abstract: This collection is necessary to comply with the applicable provisions of the RUS loan contract. Borrowers submit requisitions to RUS for funds for project costs incurred. Insured loan funds will be advanced only for projects which are included in the RUS approved borrower's construction workplan or approved amendment and in an approved loan, as amended. The process of loan advances establishes the beginning of the audit trail of the use of loan funds which is required for subsequent RUS compliance audits.

The RUS Form 595 is used as a requisition for advances of funds. The form helps to assure that loan funds are advanced only for the budget purposes and amount approved by RUS. According to the applicable provisions of the RUS loan contract, borrowers must certify with each request for funds to be approved for advance, which such funds are for projects previously approved.

When a prospective borrower requests and is granted an RUS loan, a loan contract is established between the Federal government, acting through the RUS Administrator, and the borrower. At the time this contract is entered into, the borrower must provide RUS with a list of projects for which loan funds will be spent, along with an itemized list of the estimated costs of these projects. Thus, the borrower receives a loan based upon estimated cost figures.

RUS Form 219, Inventory of Work Orders, is one of the documents the borrower submits to RUS to support actual expenditures and an advance of loan funds. The form also serves as a connecting link and provides an audit trail that originates with the advance of funds and terminates with evidence supporting the propriety of expenditures for construction or retirement projects.

Estimate of Burden: The Public reporting burden for this collection of information is estimated to average 1.57 hours per response.

Respondents: Not-for-profit institutions; Business or other for profit.

Estimated Number of Respondents: 650.

Estimated Number of Responses per Respondent: 15.42.

Estimated Total Annual Burden on Respondents: 15,745.

Copies of this information collection can be obtained from MaryPat Daskal, Program Development and Regulatory Analysis, at (202) 720–7853. Fax: (202) 720–8435. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: March 1, 2012.

James R. Newby,

Chief of Staff, Rural Utilities Service.

[FR Doc. 2012–5490 Filed 3–6–12; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Permits for Incidental Taking of Endangered or Threatened Species.

OMB Control Number: 0648–0230.

Form Number(s): NA.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 13.

Average Hours per Response: Permit applications, 80 hours; annual reports, 8 hours; permit transfers, 40 hours.

Burden Hours: 472.

Needs and Uses: This request is for an extension of a currently approved information collection.

The Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 et. seq.) imposed prohibitions against the taking of endangered species. In 1982, Congress revised the ESA to allow permits authorizing the taking of endangered species incidental to otherwise lawful activities. The corresponding regulations (50 CFR 222.222) established procedures for persons to apply for such a permit. In addition, the regulations set forth specific reporting requirements for such permit holders.

The regulations contain three sets of information collections: (l) Applications for incidental take permits, (2) applications for certificates of inclusion, and (3) reporting requirements for permits issued. Certificates of inclusion are only required if a general permit is issued to a representative of a group of potential permit applicants, rather than requiring each entity to apply for and receive a permit.

The required information is used to evaluate the impacts of the proposed activity on endangered species, to make the determinations required by the ESA prior to issuing a permit, and to establish appropriate permit conditions.

When a species is listed as threatened, section 4(d) of the ESA requires the Secretary to issue whatever regulations are deemed necessary or advisable to provide for conservation of the species. In many cases those regulations reflect blanket application of the section 9 take prohibition. However, the National Marine Fisheries Service (NMFS) recognizes certain exceptions to that prohibition, including habitat restoration actions taken in accord with approved state watershed action plans. While watershed plans are prepared for other purposes in coordination with or fulfillment of various state programs, a watershed group wishing to take advantage of the exception for restoration activities (rather than obtaining a section 10 permit) would have to submit the plan for NMFS review.

Affected Public: Not-for-profit institutions; state, local or tribal government.

Frequency: Annually and on occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: OIRA_Submission@omb.eop.gov.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: March 1, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–5457 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; 2012 National Census Test

AGENCY: U.S. Census Bureau, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, written comments must be submitted on or before May 7, 2012.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Jason Machowski, Bureau of the Census, HQ–3H468F, Washington, DC 20233; (301) 763–4173 or *jason.d.machowski@census.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau must conduct a series of research projects and tests throughout this decade to fulfill its commitment to provide the public with an option to complete their 2020 Decennial Census questionnaire on the Internet. One of the first tests to support this planning effort is the 2012 National Census Test. It has two primary objectives.

The main objective is to test new, dynamic approaches for collecting the number of people in a household, which are not feasible on a paper questionnaire. The standard paper questionnaire used in the census typically begins with a set of instructions or residence rules to guide the respondent on whom to include as members of the household as of a set reference date. Furthermore, the questionnaire later poses questions to the respondent that ask about people who the respondent may have missed (undercounted) or included by mistake (overcounted). An Internet data collection mode, on the other hand, allows the Census Bureau to guide the respondent through the residence rules using a series of questions and conditional probes, to better understand who was living in the household on the reference day.

For the 2012 National Census Test, the Census Bureau aims to optimize the presentation of its residence rules on an Internet data collection instrument and to identify validated methods for determining the appropriate number of people in a household in accordance with its residence rules. To fully assess the validity of the new approaches, a real-time, targeted, probing, coverage reinterview will be conducted by telephone with a sample of households that respond by Internet. The purpose of this reinterview is to evaluate the accuracy of within-household coverage by comparing the final household population roster collected via each Internet coverage approach to the final roster collected via telephone. The goal is to obtain a ''truth'' measure for who was living in the household on the reference day. This is the main goal of the test and other objectives will be secondary. These secondary objectives will not drive the sample size of the 2012 National Census Test.

A secondary objective of the 2012 National Census Test is to obtain response rate indicators. The Census Bureau will study the relative response rates associated with various contact strategies under a Push Internet methodology. Under a Push Internet methodology, households do not receive a questionnaire in the initial mailing. Questionnaires will be sent to households who have failed to respond on the Internet by a pre-determined date. Planned contact strategies build off previous Census and American Community Survey research and include alternate reminder and/or replacement questionnaire approaches as well as varying the timing of the replacement questionnaire. The key analytical measures expected from this data collection include response rates, return rates, percent of Internet returns, and speed of returns. More discussion on contact strategies under consideration appears in the following section, *Method of Collection*.

Without impact to sample size, the 2012 National Census Test offers the opportunity to gain knowledge about how to optimize the presentation of the race and Hispanic origin questions, as well as age and date of birth for the Internet mode.

Based on preliminary results from the 2010 Alternative Questionnaire Experiment, the combined race and Hispanic origin question approach appears to be a promising strategy for collecting these data items. The Census Bureau plans to further this research by implementing two versions of a combined race and Hispanic origin question as part of the 2012 National Census Test. In addition, this data collection will incorporate the use of predictive text (that is, the open-ended text boxes in the race and Hispanic origin questions will produce a dynamic drop-down list of suggested options based on the initial text string entered in the box). The use of predictive text will automate and streamline the race and Hispanic origin coding process. This component allows for near-real-time data processing by increasing the speed of automated coding, thus reducing and/or eliminating back-end processing.

Results from recent Census Bureau Internet studies suggest that vast improvements can be made in the presentation of age and date of birth questions in the self-response Internet mode. The Census Bureau plans to test one or two new approaches for optimizing age and date of birth presentation on the Internet. Plans include reducing the lengthy edits associated with the questions and/or using drop down menus for month, day, and year.

The results from the 2012 National Census Test will inform internal planning decisions that will guide the design of additional 2020 Decennial Census Internet testing later this decade. The results from this test will inform planning for both the next decennial census as well as the American Community Survey.

II. Method of Collection

The Census Bureau will conduct the 2012 National Census Test with a national sample of 80,000 households. The Census Bureau estimates a 45% response rate overall and a 25% Internet response rate. About one-half of Internet respondents will fall into the reinterview sample.

All contact strategy approaches tested in this data collection will be implemented using a Push Internet methodology. That is, households will receive a paper questionnaire only if they fail to respond by a predetermined date. To optimize the implementation of a Push Internet methodology, the Census Bureau will test alternatives to the standard full implementation contact strategy typically used in the decennial census (advance letter, initial mailing, reminder postcard, replacement mailing). Census Bureau

analysts will study response rates across these varying strategies with the goal of identifying the best options for use with a Push Internet methodology, which will undergo additional validation in future mid-decade census tests. Census Bureau planners have not yet finalized the contact strategy approaches for this test. The proposed plan, however, is to contact sampled households using one of six contact strategies. In addition to a control panel that uses the standard full implementation contact strategy, the experimental treatments currently under consideration are, in brief:

- Eliminating the advance letter mailing
- Adding another reminder before mailing a paper questionnaire
- Mailing the questionnaire on an accelerated schedule
- A reminder to be sent after the questionnaire mailing
- Modified wording for all mailing pieces

The Census Bureau plans to conduct the 2012 National Census Test data collection in late summer or early fall 2012. The specific data collection start and end dates along with the duration of the data collection period are still under consideration. The Census Bureau, however, expects that the duration of the data collection period will be between one and two months. This includes both the collection of self-response interviews via the Internet and paper questionnaires (returned by mail) and the real-time telephone reinterview following the Internet data collection.

III. Data

OMB Control Number: None.
Form Number: TBD.
Type of Review: Regular submission.
Affected Public: Individuals or Households.
Estimated Number of Respondents: 92,000 (80,000 initial response + 12,000 reinterview).
Estimated Time per Response: 10 minutes.
Estimated Total Annual Burden Hours: 15,334.
Estimated Total Annual Cost: There is no cost to the respondent other than his or her time.
Respondent's Obligation: Mandatory.
Legal Authority: Title 13 U.S.C. 141 and 193.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: March 2, 2012.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–5507 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

DEPARTMENT OF THE INTERIOR

Allocation of Duty-Exemptions for Calendar Year 2012 for Watch Producers Located in the United States Virgin Islands

AGENCY: Import Administration, International Trade Administration, Department of Commerce; Office of Insular Affairs, Department of the Interior.

ACTION: Notice.

SUMMARY: This action allocates calendar year 2012 duty exemptions for watch assembly producers (''program producers'') located in the United States Virgin Islands (''USVI'') pursuant to Public Law 97–446, as amended by Public Law 103–465, Public Law 106–36 and Public Law 108–429 (''the Act'').

FOR FURTHER INFORMATION CONTACT: Supriya Kumar, Subsidies Enforcement Office; phone number: (202) 482–3530; fax number: (202) 501–7952; and email address: *Supriya.Kumar@trade.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Act, the Departments of the Interior and Commerce (''the Departments'') share responsibility for the allocation of duty exemptions among program producers in the United States insular possessions and the Northern Mariana Islands.

In accordance with Section 303.3(a) of the regulations (15 CFR 303.3(a)), the total quantity of duty-free insular watches and watch movements for calendar year 2012 is 1,866,000 units for the USVI. This amount was established in *Changes in Watch, Watch Movement and Jewelry Program for the U.S. Insular Possessions,* 65 FR 8048 (February 17, 2000). There are currently no program producers in Guam, American Samoa or the Northern Mariana Islands.

The criteria for the calculation of the calendar year 2012 duty-exemption allocations among program producers within a particular territory are set forth in Section 303.14 of the regulations (15 CFR 303.14). The Departments have verified and, where appropriate, adjusted the data submitted in application form ITA–334P by USVI program producers and have inspected these producers' operations in accordance with Section 303.5 of the regulations (15 CFR 303.5).

In calendar year 2011, USVI program producers shipped 53,744 watches and watch movements into the customs territory of the United States under the Act. The dollar amount of corporate income taxes paid by USVI program producers during calendar year 2011, and the creditable wages and benefits paid by these producers during calendar year 2011 to residents of the territory was a combined total of $1,036,055.

The calendar year 2012 USVI annual duty exemption allocations, based on the data verified by the Departments, are as follows:

Program producer	Annual allocation
Belair Quartz, Inc.	500,000

The balance of the units allocated to the USVI is available for new entrants into the program or existing program producers who request a supplement to their allocation.

Dated: February 27, 2012.

Judith Wey Rudman,

Acting Director, Office of Policy, Import Administration, International Trade Administration, Department of Commerce.

Dated: February 29, 2012.

Nikolao Pula,

Director of Office of Insular Affairs, Department of the Interior.

[FR Doc. 2012–5588 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P; 4310–93–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–806]

Silicon Metal From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (''Department'') is conducting an administrative review of the antidumping duty order on silicon metal from the People's Republic of China (''PRC''). The period of review (''POR'') is June 1, 2010, through May 31, 2011. The Department has preliminarily determined that the mandatory respondent, Shanghai Jinneng International Trade Co., Ltd. (''Shanghai Jinneng''), made sales of subject merchandise to the United States at prices below normal value (''NV''). If these preliminary results are adopted in our final results of review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on entries of subject merchandise during the POR for which the importer-specific assessment rates are above *de minimis.*

We invite interested parties to comment on these preliminary results. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act'').

FOR FURTHER INFORMATION CONTACT: Rebecca Pandolph or Howard Smith, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3627, and (202) 482–5193, respectively.

SUPPLEMENTARY INFORMATION:

On June 10, 1991, the Department published the antidumping duty order on silicon metal from the PRC.[1] On June 1, 2011, the Department published a notice of opportunity to request an administrative review of the order for the June 1, 2010, through May 31, 2011 POR.[2] On June 30, 2011, the Department received a timely request from Globe Metallurgical Inc. (''Petitioner'') for an administrative review of the antidumping duty order on silicon metal from the PRC for Shanghai Jinneng.[3] On July 28, 2011, the Department initiated the administrative review of the antidumping duty order on silicon metal from the PRC for the 2010–2011 POR.[4]

On August 2, 2011, the Department issued the antidumping questionnaire to Shanghai Jinneng. Between September 2011 and January 2012, Shanghai Jinneng responded to the Department's questionnaire and supplemental questionnaires and Petitioner commented on Shanghai Jinneng's responses.

In response to the Department's September 15, 2011, letter providing parties with an opportunity to submit comments regarding surrogate country and surrogate value selection,[5] Shanghai Jinneng and Petitioner filed surrogate country and surrogate value comments on November 4, 2011 and rebuttal comments on November 14, 2011.

On November 7, 2011, the Department received a request from Petitioner to verify the information submitted by Shanghai Jinneng pursuant to 19 CFR 351.307(b)(1)(v) and for good cause.[6] On February 15, 2012, Petitioner submitted comments for the Department's consideration in the preliminary results and on February 21, 2012, Shanghai Jinneng submitted rebuttal comments.[7]

Scope of the Order

Imports covered by the order are shipments of silicon metal containing at least 96.00 but less than 99.99 percent of silicon by weight. Also covered by the order is silicon metal from the PRC containing between 89.00 and 96.00 percent silicon by weight but which contain a higher aluminum content than the silicon metal containing at least 96.00 percent but less than 99.99 percent silicon by weight. Silicon metal is currently provided for under subheadings 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule of the United States (''HTSUS'') as a chemical product, but is commonly referred to as a metal. Semiconductor-grade silicon (silicon metal containing by weight not less than 99.99 percent of silicon and provided for in subheading 2804.61.00 of the HTSUS) is not subject to the order. Although the HTSUS subheadings are provided for convenience and for customs purposes, the written description of the merchandise is dispositive.

Non-Market Economy Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as a non-market economy (''NME'') country.[8] In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. Accordingly, we calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

Separate Rates

In proceedings involving NME countries, there is a rebuttable presumption that all companies within the PRC are subject to government control and, thus, should be assessed a single antidumping duty rate.[9]

In the *Initiation Notice,* the Department notified parties of the

[1] *See Antidumping Duty Order: Silicon Metal from the People's Republic of China,* 56 FR 26649 (June 10, 1991).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 76 FR 31586 (June 1, 2011).

[3] *See* letter from Petitioner to the Secretary of Commerce, regarding ''Silicon Metal From the People's Republic of China; Request for 2010–11 Administrative Review,'' dated June 30, 2011.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Requests for Revocations in Part and Deferral of Administrative Reviews,* 76 FR 45227 (July 28, 2011) (''Initiation Notice'').

[5] *See* Letter from Howard Smith, Program Manager, Office 4, to All Interested Parties, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China,'' dated September 15, 2011 (''Surrogate Country and Values Letter'').

[6] *See* letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China; 2010–11 Administrative Review; Request for Verification,'' dated November 7, 2011. The Department responded to this request in a memorandum to the file from Rebecca Pandolph, International Trade Analyst, Office 4, AD/CVD Operations, regarding, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China,'' dated concurrently with this notice.

[7] *See* letter from Petitioner to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China; 2010–11 Administrative Review; Preliminary Results Comments,'' dated February 15, 2012 and letter from Shanghai Jinneng to the Honorable John Bryson, Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China: Shanghai Jinneng International Trade Co., Ltd.—Rebuttal to Petitioner's Comments on the Preliminary Results,'' dated February 21, 2012.

[8] *See, e.g., Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 74 FR 9591, 9593 (March 5, 2009) (unchanged in *Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 36656 (July 24, 2009)).

[9] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079 (September 8, 2006), and *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof From the People's Republic of China,* 71 FR 29303 (May 22, 2006).

application process by which exporters and producers may obtain separate rate status in NME proceedings.[10] It is the Department's policy to assign all exporters of merchandise subject to a proceeding involving an NME country a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to exports. To establish whether a company is sufficiently independent to be entitled to a separate, company-specific rate, the Department analyzes each exporting entity in an NME country under the test established in *Sparklers,*[11] as amplified by *Silicon Carbide.*[12] However, if the Department determines that a company is wholly foreign-owned or located in a market economy (''ME''), then a separate rate analysis is not necessary to determine whether it is independent from government control.[13]

Wholly Chinese-Owned

Shanghai Jinneng stated that it is a wholly Chinese-owned company.[14] Therefore, the Department must analyze whether this respondent can demonstrate the absence of both *de jure* and *de facto* governmental control over its export activities.

1. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) other formal measures by the government decentralizing control of companies.[15]

The evidence provided by Shanghai Jinneng supports a preliminary finding of a *de jure* absence of governmental control based on the following: (1) There is an absence of restrictive stipulations associated with the company's business and export licenses; (2) there are applicable legislative enactments decentralizing control of PRC companies; and (3) there are formal measures by the government decentralizing control of PRC companies.[16]

2. Absence of De Facto Control

The Department considers four factors in evaluating whether each respondent is subject to *de facto* governmental control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a governmental agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses.[17] The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of governmental control which would preclude the Department from assigning separate rates.

We determine that the evidence on the record supports a preliminary finding of a *de facto* absence of governmental control with respect to Shanghai Jinneng based on record statements and supporting documentation showing that the company: (1) Sets its own export prices independent of the government and without the approval of a government authority; (2) has the authority to negotiate and sign contracts and other agreements; (3) has autonomy from the government regarding the selection of management; and (4) retains the proceeds from its sales and makes independent decisions regarding disposition of profits or financing of losses.[18]

The evidence placed on the record of this administrative review by Shanghai Jinneng demonstrates an absence of *de jure* and *de facto* government control with respect to the company's exports of the merchandise under review, in accordance with the criteria identified in *Sparklers* and *Silicon Carbide.* Therefore, we have preliminarily granted Shanghai Jinneng separate rate status.

Selection of a Surrogate Country

Section 773(c)(1) of the Act directs the Department to base NV, in most cases, on the NME producer's factors of production (''FOP'') valued in a surrogate ME country or countries considered appropriate by the Department. In accordance with section 773(c)(4) of the Act, the Department will value FOP using ''to the extent possible, the prices or costs of factors of production in one or more market-economy countries that are—(A) at a level of economic development comparable to that of the nonmarket economy country, and (B) significant producers of comparable merchandise.'' Further, pursuant to 19 CFR 351.408(c)(2), the Department will normally value FOP in a single country.

In the instant review, the Department identified Colombia, Indonesia, the Philippines, South Africa, Thailand and Ukraine as a non-exhaustive list of countries that are at a level of economic development comparable to the PRC and for which good quality data is most likely available.[19] On January 13, 2010, Petitioner and Shanghai Jinneng proposed selecting Thailand as the surrogate country because it is at a level of economic development comparable to the PRC and is a significant producer of comparable merchandise.[20] Petitioner provided export data from Global Trade Atlas (''GTA'') demonstrating that during the POR, Thailand exported 14,022 metric tons of silicon metal worldwide.[21] With respect to data considerations, in selecting a surrogate country, it is the Department's practice that, ''* * * if more than one country has survived the selection process to this point, the country with the best factors data is selected as the primary surrogate country.''[22] Currently, the record contains surrogate value information, including a surrogate financial statement, only from Thailand. The Department is preliminarily

[10] *See Initiation Notice,* 76 FR at 45228.

[11] *See Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''*Sparklers*'').

[12] *See Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*'').

[13] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles From the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[14] *See* Letter from Shanghai Jinneng to Rebecca M. Blank, Acting Secretary of Commerce, regarding, ''Silicon Metal from the People's Republic of China: Shanghai Jinneng International Trade Co., Ltd.—Section A Questionnaire Response,'' dated August 30, 2011 (''Section A Response'') at 2.

[15] *See Sparklers,* 56 FR at 20589.

[16] *See* Section A Response at 5–10.

[17] *See Silicon Carbide,* 59 FR at 22586–87; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995).

[18] *See* Section A Response at 5–10.

[19] *See* Surrogate Country and Values Letter at Attachment 1.

[20] *See* letter from Shanghai Jinneng to Rebecca M. Blank, Acting Secretary of Commerce regarding, ''Silicon Metal from the People's Republic of China,'' dated November 4, 2011 (''Shanghai Jinneng's SV Comments'') at 1–2 and letter from Petitioner to John Bryson, Secretary of Commerce regarding, ''Silicon Metal from the People's Republic of China; 2010–11 Administrative Review; Comments on Surrogate Country Selection and Submission of Surrogate Value Data'' dated November 4, 2011 (''Petitioner's SV Comments'').

[21] *See* Petitioner's SV Comments at 4 and Exhibit 4.

[22] *See* Policy Bulletin 04.1: Non-Market Economy Surrogate Country Selection Process, (March 1, 2004) available at *http://ia.ita.doc.gov.*

selecting Thailand as the surrogate country on the basis that: (1) It is at a comparable level of economic development to the PRC, pursuant to section 773(c)(4)(A) of the Act; (2) it is a significant producer of comparable merchandise, pursuant to section 733(c)(4)(B) of the Act; and (3) we have reliable data from Thailand that we can use to value the FOP. Therefore, we have calculated NV using Thai prices, when available and appropriate, to value Shanghai Jinneng's FOP.[23] In accordance with 19 CFR 351.301(c)(3)(ii), interested parties may submit publicly available information to value FOP until 20 days after the date of publication of the preliminary results.[24]

Fair Value Comparisons

In accordance with section 777A(d)(2) of the Act, to determine whether Shanghai Jinneng sold silicon metal to the United States at less than fair value, we compared the export price (''EP'') of the silicon metal to the NV of the silicon metal, as described in the ''Export Price,'' and ''Normal Value'' sections of this notice.

Export Price

In accordance with section 772(a) of the Act, we used EP for all sales reported by Shanghai Jinneng. We calculated EP based on the packed prices to unaffiliated purchasers in, or for exportation to, the United States. We made deductions, as appropriate, for any movement expenses (*e.g.,* foreign inland freight from the plant to the port of exportation, domestic brokerage, international freight to the port of importation) in accordance with section 772(c)(2)(A) of the Act. Where foreign inland freight or foreign brokerage and handling fees were provided by PRC service providers or paid for in renminbi, we based those charges on surrogate values.[25]

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine NV using an FOP methodology if the merchandise is exported from an NME country and the available information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. When determining NV in an NME context, the Department uses an FOP methodology because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under its normal methodologies.[26] Under section 773(c)(3) of the Act, FOP include, but are not limited to: (1) Hours of labor required; (2) quantities of raw materials employed; (3) amounts of energy and other utilities consumed; and (4) representative capital costs. The Department based NV on FOP reported by Shanghai Jinneng for materials, energy, labor and packing.

Factor Valuation Methodology

In accordance with section 773(c) of the Act, we calculated NV by adding together the values of the FOPs, general expenses, profit, and packing costs. We calculated FOP values by multiplying the reported per-unit factor-consumption rates by publicly available surrogate values (except as discussed below). In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data.[27] As appropriate, we adjusted input prices by including freight costs to make them delivered prices. Specifically, we added to Thai import surrogate values a Thai surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate. This adjustment is in accordance with the Court of Appeals for the Federal Circuit's (''CAFC'') decision in *Sigma Corp.* v. *United States,* 117 F.3d 1401, 1407–08 (Fed. Cir. 1997). A detailed description of all surrogate values used for Shanghai Jinneng can be found in the Surrogate Value Memorandum.

In selecting the best available information for valuing FOP in accordance with section 773(c)(1) of the Act, the Department's practice is to select, to the extent practicable, surrogate values which are non-export average values, contemporaneous or closest in time with the POR, product-specific, and tax-exclusive.[28] The record shows that import data from Thailand's Customs Department, as published by the GTA, as well as data from other Thai sources used, are typically contemporaneous with the POR, product-specific or for similar products, and tax-exclusive.[29] Thus, for these preliminary results, in accordance with its practice, the Department used data from the Thailand Customs Department and other publicly available sources from Thailand in order to calculate surrogate values for Shanghai Jinneng's FOP (direct materials and packing materials) and certain movement expenses.[30] In those instances where we could not obtain publicly available surrogate values contemporaneous with the POR with which to value FOPs, we adjusted the surrogate values using, where appropriate, the International Monetary Fund's Consumer Price Index (''CPI'') for Thailand.[31]

Furthermore, with regard to Thailand's import-based surrogate values, we have disregarded import prices that we have reason to believe or

[23] *See* Memorandum to the File through Howard Smith, Program Manager, AD/CVD Operations, Office 4, from Rebecca Pandolph, International Trade Compliance Analyst, regarding ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China: Factor Valuation Memorandum,'' dated March 1, 2012 (''Surrogate Value Memorandum'').

[24] Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent-from-the-record alternative surrogate value information pursuant to 19 CFR 351.301(c)(1). *See Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007) and accompanying Issues and Decision Memorandum (''IDM'') at Comment 2. Additionally, for each piece of factual information submitted with surrogate value rebuttal comments, the Department is hereby requesting that the interested party provide a written explanation of what information that is already on the record of the ongoing proceeding the factual information is rebutting, clarifying, or correcting.

[25] *See* the ''Factor Valuation Methodology'' section for further discussion of surrogate values.

[26] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value, Affirmative Critical Circumstances, In Part, and Postponement of Final Determination: Certain Lined Paper Products from the People's Republic of China,* 71 FR 19695, 19703 (April 17, 2006) (unchanged in *Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079 (September 8, 2006)).

[27] *See, e.g., New Pneumatic Off-the-Road Tires from the People's Republic of China: Final Affirmative Determination of Sales at Less than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 40485 (July 15, 2008), and accompanying IDM at Comment 9.

[28] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 42672, 42682 (July 16, 2004) (unchanged in *Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from the Socialist Republic of Vietnam,* 69 FR 71005 (December 8, 2004)).

[29] *See* Surrogate Value Memorandum at 3–6.

[30] *See* Surrogate Value Memorandum at 1–2 and Attachment 1.

[31] *See* Surrogate Value Memorandum at 2 and Attachment 3.

suspect may be subsidized. We have reason to believe or suspect that prices of inputs from India, Indonesia, South Korea, and Thailand may have been subsidized. We have found in other proceedings that these countries maintain broadly available, non-industry-specific export subsidies and, therefore, it is reasonable to infer that all exports to all markets from these countries may be subsidized.[32]

Further, guided by the legislative history, it is the Department's practice not to conduct a formal investigation to ensure that such prices are not subsidized.[33] Rather, the Department bases its decision on information that is available to it at the time it makes its determination.[34] Therefore, we have not used prices from India, Indonesia, or South Korea in calculating Thailand's import-based surrogate values. Additionally, we disregarded prices from NME countries. Furthermore, imports that were labeled as originating from an ''unspecified'' country were excluded from the average value, because the Department could not be certain that they were not from either an NME country or a country with general export subsidies.[35] Lastly, the Department has also excluded imports from Thailand into Thailand because there is no evidence on the record regarding what these data represent (*e.g.,* re-importations, another category of unspecified imports, or the result of an error in reporting). Thus, these data do not represent the best available information upon which to rely for valuation purposes.[36]

Previously to value the respondent's cost of labor, the Department used regression-based wages that captured the worldwide relationship between *per capita* Gross National Income (''GNI'') and hourly manufacturing wages, pursuant to 19 CFR 351.408(c)(3). However, on May 14, 2010, the CAFC, in *Dorbest Ltd.* v. *United States,* 604 F.3d 1363, 1372 (Fed. Cir. 2010) (''*Dorbest*''), invalidated 19 CFR 351.408(c)(3). As a consequence of the CAFC's ruling in *Dorbest,* the Department no longer relies on the regression-based wage rate methodology described in its regulations. On February 18, 2011, the Department published in the **Federal Register** a request for public comment on the interim methodology, and the data sources.[37]

On June 21, 2011, the Department revised its methodology for valuing the labor input in NME antidumping proceedings.[38] In *Labor Methodologies,* the Department determined that the best methodology to value the labor input is to use industry-specific labor rates from the primary surrogate country. Additionally, the Department determined that the best data source for industry-specific labor rates is Chapter 6A: Labor Cost in Manufacturing, from the International Labor Organization (''ILO'') Yearbook of Labor Statistics (''Yearbook'').

In these preliminary results, the Department calculated the labor input using the data on industry specific labor cost from the primary surrogate country (*i.e.,* Thailand), as described in *Labor Methodologies*. The Department relied on Chapter 6A labor cost data for Thailand from the ILO's Yearbook. The Department used ILO Chapter 6A labor cost data for the year 2000 because this is the most recent Chapter 6A data available for Thailand. The Department further determined that the two-digit description under ISIC–Revision 3–D (''Manufacture of Basic Metals'') is the best available information because it is specific to the industry being examined and, therefore, is derived from industries that produce comparable merchandise. Accordingly, relying on Chapter 6A of the Yearbook, the Department calculated the labor input using labor cost data reported by Thailand to the ILO under Sub-Classification 27 of the ISIC–Revision 3–D, in accordance with section 773(c)(4) of the Act. For these preliminary results, the calculated industry-specific wage rate is 81.96 baht per hour. The Department inflated this value to the POR using Thai CPI data. For further information on the calculation of the wage rate, *see* Surrogate Value Memorandum at 5.

The ILO data from Chapter 6A of the Yearbook, which was used to value labor, reflects all costs related to labor, including wages, benefits, housing, training, *etc.* The financial statement used to calculate the surrogate financial ratios does not include itemized details regarding the indirect labor costs incurred. Therefore, the Department has not made adjustments to the surrogate financial ratios.

We valued all packing and direct materials, except quartz, using Thai import data from the GTA that are contemporaneous with the POR. We valued quartz using the price of unground quartz in 2010 from *Mineral Statistics of Thailand 2006–2010* report issued by the Thai Department of Primary Industries and Mines.[39]

We valued electricity using data from the Thai Provincial Electricity Authority and Electricity Generating Authority of Thailand as reported by the Thailand Board of Investment in its 2011 publication *Costs of Doing Business in Thailand* for large general services at a voltage of 22–33 kilovolts. These electricity rates represent actual country-wide, publicly available information on tax-exclusive electricity rates in Thailand. As the rates were in effect during the POR, we are not adjusting the average value for inflation.[40]

We valued truck freight expenses using a per-unit average rate from the Express Transportation Organization of Thailand as reported in Thailand Board of Investment's 2011 publication, *Costs of Doing Business in Thailand*.[41] Because the rate is from August 2005, we inflated this rate to a POR rate using Thai CPI data.

We valued railway freight using price data from State Railway of Thailand as reported in Thailand Board of Investment's 2011 publication, *Costs of*

[32] *See Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Color Television Receivers From the People's Republic of China,* 69 FR 20594 (April 16, 2004), and accompanying IDM at Comment 7; *see also Carbazole Violet Pigment 23 from India: Final Results of the Expedited Five-year (Sunset) Review of the Countervailing Duty Order,* 75 FR 13257 (March 19, 2010), and accompanying IDM at 4–5; *Certain Cut-to-Length Carbon Quality Steel Plate from Indonesia: Final Results of Expedited Sunset Review,* 70 FR 45692 (August 8, 2005), and accompanying IDM at 4; *Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review,* 74 FR 2512 (January 15, 2009), and accompanying IDM at 17, 19–20.

[33] *See* Omnibus Trade and Competitiveness Act of 1988, Conference Report to accompany H.R. Rep. 100–576 at 590 (1988) reprinted in 1988 U.S.C.C.A.N. 1547, 1623–24; *see also Preliminary Determination of Sales at Less Than Fair Value: Coated Free Sheet Paper from the People's Republic of China,* 72 FR 30758 (June 4, 2007) (unchanged in *Final Determination of Sales at Less Than Fair Value: Coated Free Sheet Paper from the People's Republic of China,* 72 FR 60632 (October 25, 2007)).

[34] *See Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 73 FR 24552, 24559 (May 5, 2008) (unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 73 FR 55039 (September 24, 2008)).

[35] *Id.*

[36] *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 75 FR 47771 (August 9, 2010) and accompanying Issues and Decision Memorandum at Comment 6.

[37] *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor, Request for Comment,* 76 FR 9544 (February 18, 2011).

[38] *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (''*Labor Methodologies*'').

[39] *See* Surrogate Value Memorandum at 4.

[40] *See* Surrogate Value Memorandum at 6.

[41] *See* Surrogate Value Memorandum at 7.

Doing Business in Thailand.[42] Because the rate is from August 2011, we deflated it to the POR using Thai CPI data.

We valued ocean freight using price data from Profreight International Co., Ltd., as reported in Thailand Board of Investment's 2011 publication, *Costs of Doing Business in Thailand*.[43]

We valued brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods in Thailand for a 20 foot container published in the World Bank publication, *Doing Business 2012: Thailand*.[44]

Lastly, we valued selling, general and administrative expenses, factory overhead costs, and profit using the contemporaneous 2010 financial statement of GS Energy Co., Ltd., a Thai producer of silicon metal, which is identical to subject merchandise.[45]

Currency Conversion

Where necessary, we made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.[46]

Preliminary Results of Review

We preliminarily determine that the following dumping margin exists for the period June 1, 2010 through May 31, 2011.

SILICON METAL FROM THE PRC

Exporter	Margin (percentage)
Shanghai Jinneng International Trade Co., Ltd.	5.5

Disclosure

The Department intends to disclose calculations performed for these preliminary results to the parties within 10 days of the date of the public announcement of the results of this review in accordance with 19 CFR 351.224(b).

Comments

Interested parties may submit written comments no later than 30 days after the date of publication of these preliminary results of review.[47] Rebuttal comments must be limited to the issues raised in the written comments and may be filed no later than five days after the time limit for filing the case briefs.[48] Interested parties, who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, filed electronically using Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern Standard Time within 30 days after the date of publication of this notice.[49] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.[50] Parties should confirm by telephone the date, time, and location of the hearing. The Department will issue the final results of the administrative review, which will include the results of its analysis of issues raised in the briefs, within 120 days of publication of these preliminary results, in accordance with section 751(a)(3)(A) of the Act, unless the time limit is extended.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. In accordance with 19 CFR 351.212(b)(1), we are calculating customer-specific assessment rates for the merchandise subject to this review. Because we do not have entered values for all U.S. sales to a particular importer/customer, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[51] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated customer-specific *ad valorem* ratios based on the estimated entered value. Where a customer-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[52]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporter listed above, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 139.49[53] percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

The Department is issuing and publishing these preliminary results of administrative review in accordance with sections751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

[42] *See* Surrogate Value Memorandum at 8.

[43] *See* Surrogate Value Memorandum at 8.

[44] *See* Surrogate Value Memorandum at 6.

[45] *See* Surrogate Value Memorandum at 10.

[46] *See* Surrogate Value Memorandum at 2.

[47] *See* 19 CFR 351.309(c)(1)(ii).

[48] *See* 19 CFR 351.309(d).

[49] *See* 19 CFR 351.310(c).

[50] *See* 19 CFR 351.310.

[51] *See* 19 CFR 351.212(b)(1).

[52] *See* 19 CFR 351.106(c)(2).

[53] *See Final Determination of Sales at Less Than Fair Value: Silicon Metal from the People's Republic of China,* 56 FR 18570, 18571–2 (April 23, 1991).

Dated: March 1, 2012.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. 2012–5582 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–933]

Frontseating Service Valves From the People's Republic of China: Notice of Second Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* March 7, 2012.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita or Brooke Kennedy, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4243 or (202) 482–3818, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 27, 2011, the Department of Commerce (''the Department'') published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on frontseating service valves from the People's Republic of China for the period April 1, 2010, through March 31, 2011.[1] On December 13, 2011, the Department extended the deadline for the preliminary results by 90 days, to March 30, 2012.[2]

Extension of Time Limit of Preliminary Results

Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), the Department shall make a preliminary determination in an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the date of publication of the order. The Act further provides, however, that the Department may extend that 245-day period to 365 days if it determines it is not practicable to complete the review within the foregoing time period.

We determine that completion of the preliminary results of this review by March 30, 2012, is not practicable because the Department requires additional time to analyze information pertaining to the respondents' sales practices, factors of production, as well as issue and review responses to supplemental questionnaires. Therefore, in accordance with section 751(a)(3)(A) of the Act, we are extending the time limit for completion of the preliminary results of this administrative review by 30 additional days, until April 29, 2012. However, because April 29, 2012, falls on a weekend, the preliminary results are now due no later than April 30, 2012.[3]

This notice is published in accordance with sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: March 1, 2012.

Gary Taverman,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–5580 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–868]

Folding Metal Tables and Chairs From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on folding metal tables and chairs from the People's Republic of China (''PRC''). The period of review (''POR'') is June 1, 2010, through May 31, 2011. The 2010–2011 administrative review covers Feili Group (Fujian) Co., Ltd. and Feili Furniture Development Limited Quanzhou City (collectively, ''Feili''). We have preliminarily determined that Feili made sales in the United States at prices below normal value (''NV'') during the period of review (''POR''). If these preliminary results are adopted in our final results of the review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise during the POR.

We invite interested parties to comment on these preliminary results. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act'').

DATES: *Effective Date:* March 7, 2012.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian or Charles Riggle, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6412 and (202) 482–0650, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 27, 2002, the Department published the antidumping duty order on folding metal tables and chairs from the PRC.[1] On June 1, 2010, the Department published a notice of opportunity to request an administrative review of this order for the period June 1, 2009, through May 31, 2010.[2] In accordance with 19 CFR 351.213(b), interested parties made the following requests for an administrative review: (1) On June 28, 2011, Meco Corporation (''Meco''), a domestic producer of the like product, requested that the Department conduct an administrative review of Feili and of New-Tec Integration (Xiamen) Co., Ltd. (New-Tec), a producer and exporter of subject merchandise to the United States; (2) on June 29, 2011, Feili requested that the Department conduct an administrative review of its sales; (3) on June 30, 2011, Cosco Home & Office Products (''Cosco''), a U.S. importer of subject merchandise, requested that the Department conduct an administrative review of Feili and New-Tec; and (4) on June 30, 2011, New-Tec requested that the Department revoke the antidumping duty order with respect to exports of subject merchandise manufactured and exported by New-Tec and defer the initiation of its review for the current POR. On July 28, 2011, the Department initiated the 2010–2011 review for Feili

[1] See Initiation of Antidumping and Countervailing Duty Administrative Reviews, 76 FR 30912 (May 27, 2011).

[2] *See Frontseating Service Valves from the People's Republic of China: Extension of Time for the Preliminary Results of the Antidumping Duty Administrative Review,* 76 FR 77479 (December 13, 2011).

[3] *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[1] *See Antidumping Duty Order: Folding Metal Tables and Chairs From the People's Republic of China,* 67 FR 43277 (June 27, 2002).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 76 FR 31586 (June 1, 2011).

and deferred the review of New-Tec.[3] On October 25, 2011, the Department revoked the order with respect to New-Tec and subsequently corrected language in the original revocation.[4]

The Department issued an antidumping duty questionnaire to Feili on August 26, 2011. On September 16, 2011, Feili submitted a section A questionnaire response (''AQR''), and on October 17, 2011, submitted section C and D questionnaire responses (''CQR'' and ''DQR,'' respectively). On December 2, 2011, and January 9, 2012, Feili submitted supplemental questionnaire responses (''SQR'' and ''SSQR,'' respectively).

On September 30, 2011, the Department requested that Import Administration's Office of Policy to provide a list of surrogate countries for the administrative review.[5] On October 12, 2011, the Office of Policy issued its list of surrogate countries for the administrative review.[6]

On October 25, 2011, the Department requested interested parties to submit surrogate value (''SV'') information and to provide surrogate country selection comments for the administrative review. On November 8, 2011, Feili commented on surrogate country selection. On November 15, 2011, Cosco and Feili provided financial statements from India and Thailand to be used for the calculation of surrogate financial ratios. On December 28, 2011, the Department provided additional time to submit publicly available information to value the factors of production (''FOP''). On January 17, 2012, Cosco provided additional comments on FOPs.

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results in an antidumping administrative review or new shipper review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results of review.

Period of Review

The POR is June 1, 2010, through May 31, 2011.

Scope of Order

The products covered by the order consist of assembled and unassembled folding tables and folding chairs made primarily or exclusively from steel or other metal, as described below:

(1) Assembled and unassembled folding tables made primarily or exclusively from steel or other metal (folding metal tables). Folding metal tables include square, round, rectangular, and any other shapes with legs affixed with rivets, welds, or any other type of fastener, and which are made most commonly, but not exclusively, with a hardboard top covered with vinyl or fabric. Folding metal tables have legs that mechanically fold independently of one another, and not as a set. The subject merchandise is commonly, but not exclusively, packed singly, in multiple packs of the same item, or in five piece sets consisting of four chairs and one table. Specifically excluded from the scope of the order regarding folding metal tables are the following:

Lawn furniture; Trays commonly referred to as ''TV trays;'' Side tables; Child-sized tables; Portable counter sets consisting of rectangular tables 36'' high and matching stools; and, Banquet tables. A banquet table is a rectangular table with a plastic or laminated wood table top approximately 28″ to 36″ wide by 48″ to 96″ long and with a set of folding legs at each end of the table. One set of legs is composed of two individual legs that are affixed together by one or more cross-braces using welds or fastening hardware. In contrast, folding metal tables have legs that mechanically fold independently of one another, and not as a set.

(2) Assembled and unassembled folding chairs made primarily or exclusively from steel or other metal (folding metal chairs). Folding metal chairs include chairs with one or more cross-braces, regardless of shape or size, affixed to the front and/or rear legs with rivets, welds or any other type of fastener. Folding metal chairs include: those that are made solely of steel or other metal; those that have a back pad, a seat pad, or both a back pad and a seat pad; and those that have seats or backs made of plastic or other materials. The subject merchandise is commonly, but not exclusively, packed singly, in multiple packs of the same item, or in five piece sets consisting of four chairs and one table. Specifically excluded from the scope of the order regarding folding metal chairs are the following:

Folding metal chairs with a wooden back or seat, or both; Lawn furniture; Stools; Chairs with arms; and Child-sized chairs.

The subject merchandise is currently classifiable under subheadings 9401.71.0010, 9401.71.011, 9401.71.0030, 9401.71.0031, 9401.79.0045, 9401.79.0046, 9401.79.0050, 9403.20.0018, 9403.20.0015, 9403.20.0030, 9403.60.8040, 9403.70.8015, 9403.70.8020, and 9403.70.8031 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise is dispositive.

Non-Market Economy Country Status

No party contested the Department's treatment of the PRC as a non-market economy (''NME'') country, and the Department has treated the PRC as an NME country in all past antidumping duty investigations and administrative reviews.[7] Designation as an NME country remains in effect until it is revoked by the Department. *See* section 771(18)(C)(i) of the Act. As such, we continue to treat the PRC as a NME in this proceeding.

Surrogate Country

Section 773(c)(1) of the Act directs the Department to base NV on the NME producer's FOPs, valued in a surrogate market economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall use, to the extent possible, the prices or costs of the FOPs in one or more market economy countries that are: (1) At a level of economic development comparable to that of the NME country; and (2) significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the ''Normal Value'' section below as well as in the Surrogate Value Memorandum.[8]

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[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Requests for Revocations in Part and Deferral of Administrative Reviews,* 76 FR 45227 (July 28, 2010) (''*Initiation Notice*'').

[4] *See Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review, and Revocation of the Order in Part,* 76 FR 66036 (October 25, 2011) and *Folding Metal Tables and Chairs From the People's Republic of China: Notice of Correction to the Final Results of the 2009–2010 Antidumping Duty Administrative Review,* 76 FR 72903 (November 28, 2011).

[5] *See* Memorandum to Carole Showers, Director, Office of Policy, entitled, ''2010–2011 Administrative Review of the Antidumping Duty Order on Folding Metal Tables and Chairs from the People's Republic of China: Request for Surrogate Country Selection,'' dated September 30, 2011.

[6] *See* Memorandum from Carole Showers, Director, Office of Policy, entitled, ''Request for a List of Surrogate Countries for an Administrative Review of Folding Metal Tables and Chairs (''FMTC'') from the People's Republic of China (PRC),'' dated October 12, 2011 (''Surrogate Country Memorandum'').

[7] *See, e.g., Chlorinated Isocyanurates from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 73 FR 52645 (September 10, 2008); *see also Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 3560 (January 21, 2009).

[8] *See* Memorandum to The File entitled, ''Preliminary Results of the 2010–2011

The Department determined that the Colombia, Indonesia, Philippines, South Africa, Thailand, and Ukraine are countries comparable to the PRC in terms of economic development.[9] Once we have identified the countries that are economically comparable to the PRC, we select an appropriate surrogate country by determining whether an economically comparable country is a significant producer of comparable merchandise and whether the data for valuing FOPs are both available and reliable. Accordingly, unless we find that all of the countries determined to be equally economically comparable are not significant producers of comparable merchandise, do not provide a reliable source of publicly available surrogate data or are unsuitable for use for other reasons, we will rely on data from one of these countries.

The Department has determined that Thailand is the appropriate surrogate country for use in this review. The Department based its decision on the following facts: (1) Thailand is at a level of economic development comparable to that of the PRC; (2) Thailand is a significant producer of comparable merchandise (i.e., steel furniture); and (3) Thailand provides the best opportunity to use quality, publicly available data to value the FOPs.[10] Feili has argued that the Department should continue using India as the surrogate country as it has in the previous administrative reviews. Cosco stated that the Department should use Thailand but that it would not object if the Department used India as the surrogate country. Because Thailand satisfies the Department's criteria for the selection of a primary surrogate country, resort to an alternative surrogate country which is not as economically comparable to the PRC as the countries on the Surrogate Country List, as suggested by Feili, is not necessary. Furthermore, it satisfies the best data availability criterion as the record contains usable financial statements from Thailand [11] and sources for valuation of all factors of production. As we do not have financial statements and energy inputs on the record of this review from any other country on the list of economically comparable surrogate countries, we find that Thailand is the only country that satisfies the best data availability criterion for the surrogate country.

Separate Rates

In proceedings involving NME countries, the Department has a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assessed a single antidumping duty rate.[12] It is the Department's policy to assign all exporters of merchandise subject to review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.[13] Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities. The Department analyzes each entity exporting the subject merchandise under a test arising from the *Notice of Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588, at Comment 1 (May 6, 1991) (''*Sparklers*''), as further developed in *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585, 22587 (May 2, 1994) (''*Silicon Carbide*''). However, if the Department determines that a company is wholly foreign-owned or located in a market economy, then a separate-rate analysis is not necessary to determine whether it is independent from government control.[14]

Feili reported that it is a wholly owned by a market-economy entity. Therefore, consistent with the Department's practice, a separate-rates analysis is not necessary to determine whether Feili's export activities are independent from government control, and we have preliminarily granted a separate rate to Feili.

Date of Sale

According to 19 CFR 351.401(i),

In identifying the date of sale of the subject merchandise or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the ordinary course of business. However, the Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale.

See also Allied Tube and Conduit Corp. v. *United States,* 132 F. Supp. 2d 1087, 1090–1092 (CIT 2001) (upholding the Department's rebuttable presumption that invoice date is the appropriate date of sale). After examining the questionnaire responses and the sales documentation placed on the record by Feili, we preliminarily determine that invoice date is the most appropriate date of sale for Feili. Nothing on the record of this segment rebuts the presumption that invoice date should be the date of sale.

Normal Value Comparisons

To determine whether sales of folding metal tables and chairs to the United States by Feili were made at less than NV, we compared export price (''EP'') to NV, as described in the ''Export Price,'' and ''Normal Value'' sections of this notice, pursuant to section 771(35) of the Act.

Export Price

Because Feili sold subject merchandise to unaffiliated purchasers in the United States prior to importation into the United States or to unaffiliated resellers outside the United States with knowledge that the merchandise was destined for the United States, and use of a constructed export price methodology is not otherwise indicated, we have used EP for Feili in accordance with section 772(a) of the Act.

We calculated EP based on the free-on-board or delivered price to unaffiliated purchasers for Feili. From this price, we deducted amounts for foreign inland freight and brokerage and handling, as applicable, pursuant to section 772(c)(2)(A) of the Act.[15]

The Department valued brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods in Thailand. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India that is in *Doing*

Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: Surrogate Value Memorandum,'' dated concurrently with this notice (''Prelim SV Memo'').

[9] *See* Surrogate Country Memorandum. The Department notes that these six countries are part of a non-exhaustive list of countries that are at a level of economic development comparable to the PRC.

[10] *See* Prelim SV Memo at Attachment II, and Cosco's January 17, 2012 surrogate value submission at 3.

[11] *See* financial statements of Siam Steel International PCL (''Siam''), for the fiscal year ending June 30, 2011.

[12] *See, e.g., Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 75 FR 24892, 24899 (May 6, 2010).

[13] *Id.*

[14] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles From the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[15] *See* Memorandum to The File entitled, ''Analysis for the Preliminary Results of the 2010–2011 Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: Feili Group (Fujian) Co., Ltd. and Feili Furniture Development Limited Quanzhou City,'' at 3–4, dated concurrently with this notice (''Preliminary Analysis Memorandum'').

Business 2011: Thailand, published by the World Bank.[16]

Zero-Priced Transactions

In the final results of previous administrative reviews of folding metal tables and chairs, we included Feili's zero-priced transactions in the margin calculation because the record demonstrated that respondents provided the same merchandise in significant quantities, indicating that these ''samples'' did not primarily serve for evaluation or testing of the merchandise.[17] Additionally, respondents provided ''samples'' to the same customers to whom they were selling the same products in commercial quantities.[18] As a result, we concluded that these transactions were not what we consider to be samples because respondents were providing these products to strengthen their customer relationships and to promote future sales.

With respect to zero-priced transactions, the Court of International Trade (''CIT'') in *NSK Ltd.* v. *United States* stated that it saw ''little reason in supplying and re-supplying and yet re-supplying the same product to the same customer in order to solicit sales if the supplies are made in reasonably short periods of time,'' and that ''it would be even less logical to supply a sample to a client that has made a recent bulk purchase of the very item being sampled by the client.'' [19] Moreover, even where the Department does not ask a respondent for specific information to demonstrate that a transaction is a sample, the respondent has the burden of presenting the information in the first place to demonstrate that its transactions qualify for exclusion as a sample.[20]

An analysis of Feili's section C computer sales listings reveals that in some cases it provided zero-priced merchandise to customers to whom it was already selling the same products in commercial quantities, indicating that Feili was not providing this zero-priced merchandise for a customer's evaluation and testing, with the hope of future sales. Consequently, based on the facts cited above, the guidance of past court decisions, and our previous decisions, we have not excluded these zero-priced transactions from the margin calculations for Feili for the preliminary results of this review. However, we found that, in some instances, Feili shipped merchandise to customers for the first time in non-commercial quantities. Therefore, we have treated these sales as samples for the preliminary results.[21]

Normal Value

Section 773(c)(1) of the Act provides that, in the case of an NME, the Department shall determine NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act.

The Department bases NV on FOPs because the presence of government controls on various aspects of NME economies renders price comparisons and the calculation of production costs invalid under our normal methodologies. Therefore, in these preliminary results, we have calculated NV based on FOPs in accordance with sections 773(c)(3) and (4) of the Act and 19 CFR 351.408(c). The FOPs include: (1) Hours of labor required; (2) quantities of raw materials employed; (3) amounts of energy and other utilities consumed; and (4) representative capital costs. In accordance with 19 CFR 351.408(c)(1), the Department normally uses publicly available information to value the FOPs. However, when a producer sources a meaningful amount of an input from a market-economy country and pays for it in market-economy currency, the Department may value the factor using the actual price paid for the input.[22]

In accordance with the *OTCA 1988* legislative history, the Department continues to apply its long-standing practice of disregarding SVs if it has a reason to believe or suspect the source data may be subsidized.[23] In this regard, the Department has previously found that it is appropriate to disregard such prices from India, Indonesia, South Korea and Thailand because we have determined that these countries maintain broadly available, non-industry specific export subsidies.[24] Based on the existence of these subsidy programs that were generally available to all exporters and producers in these countries at the time of the POR, the Department finds that it is reasonable to infer that all exporters from India, Indonesia, South Korea and Thailand may have benefitted from these subsidies.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on the FOPs reported by Feili during the POR. To calculate NV, we multiplied the reported per-unit factor quantities by publicly available Thai surrogate values (except as noted below). In selecting the SVs, we considered the quality, specificity, public availability, and contemporaneity of the data. As appropriate, we adjusted input prices by including freight costs to render them delivered prices. Specifically, we added to Thai import SVs a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate (*i.e.,* where the sales terms for the market-economy inputs were not delivered to the factory). This adjustment is in accordance with the decision of the CAFC in *Sigma Corp.* v. *United States,* 117 F. 3d 1401, 1408 (Fed. Cir. 1997). For a detailed description of all SVs used for Feili, see the Surrogate Value Memorandum.

For the preliminary results, except where noted below, we used data from the Thai Import Statistics in the Global Trade Atlas (''GTA'') and other publicly available Thai sources in order to calculate SVs for Feili's FOPs (i.e.,

[16] *See* Prelim SV Memo at 5 and Preliminary Analysis Memorandum at 7–8.

[17] *See, e.g., Folding Metal Tables and Chairs from the People's Republic of China; Final Results of Antidumping Duty Administrative Review,* 71 FR 2905 (January 18, 2006), and accompanying Issues and Decision Memorandum at Comment 4; *Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 71 FR 71509 (December 11, 2006), and accompanying Issues and Decision Memorandum at Comment 4; and *Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 72 FR 71355 (December 17, 2007), and accompanying Issues and Decision Memorandum at Comments 10 and 11.

[18] *Id.*

[19] *See NSK Ltd.* v. *United States,* 217 F. Supp. 2d 1291, 1311–1312 (CIT 2002).

[20] *See NTN Bearing Corp. of America.* v. *United States,* 997 F.2d 1453, 1458 (Fed. Cir. 1993).

[21] *See* Preliminary Analysis Memorandum at 2–3.

[22] *See* 19 CFR 351.408(c)(1); *see also Lasko Metal Products* v. *United States,* 43 F.3d 1442, 1445–1446 (Fed. Cir. 1994) (affirming the Department's use of market-based prices to value certain FOPs).

[23] *See* Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) (''*OTCA 1988*'') at 590.

[24] *See, e.g., Expedited Sunset Review of the Countervailing Duty Order on Carbazole Violet Pigment 23 from India,* 75 FR 13257 (March 19, 2010) and accompanying Issues and Decision Memorandum at pages 4–5; *Expedited Sunset Review of the Countervailing Duty Order on Certain Cut-to-Length Carbon Quality Steel Plate from Indonesia,* 70 FR 45692 (August 8, 2005) and accompanying Issues and Decision Memorandum at 4; *See also Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review,* 74 FR 2512 (January 15, 2009) and accompanying Issues and Decision Memorandum at 17, 19–20; *See also Certain Hot-Rolled Carbon Steel Flat Products from Thailand: Final Results of Countervailing Duty Determination,* 66 FR 50410 (October 3, 2001), and accompanying Issues and Decision Memorandum at 23.

direct materials, energy, and packing materials) and certain movement expenses. As Thailand is the primary surrogate country, we used Thai data. In selecting the best available information for valuing FOPs in accordance with section 773(c)(1) of the Act, the Department's practice is to select, to the extent practicable, SVs which are non-export average values, most contemporaneous with the POR, product-specific, and tax-exclusive.[25] The record shows that data in the Thai Import Statistics are contemporaneous with the POR, product-specific, and tax-exclusive.[26] In those instances where we could not obtain publicly available information contemporaneous to the POR with which to value factors, we adjusted the SVs using, where appropriate, the Thai Consumer Price Index (''CPI'') as published in the IMF's *International Financial Statistics*.[27]

Feili reported purchases of raw materials produced in market-economy countries, sourced from market-economy suppliers and paid for in a market-economy currency during the POR. In accordance with our practice outlined in *Antidumping Methodologies: Market Economy Inputs,*[28] when at least 33 percent of an input is sourced from market-economy suppliers and purchased in a market-economy currency, the Department will use actual market-economy purchase prices to value these inputs.[29] Where the quantity of the reported input purchased from ME suppliers is below 33 percent of the total volume of the input purchased from all sources during the POI, and were otherwise valid, we weight-average the ME input's purchase price with the appropriate SV for the input according to their respective shares of the reported total volume of purchases.[30] Therefore, the Department has valued certain inputs using the market-economy purchase prices reported by Feili, where appropriate.

On June 21, 2011, the Department revised its methodology for valuing the labor input in NME antidumping proceedings.[31] In *Labor Methodologies,* the Department determined that the best methodology to value the labor input is to use industry-specific labor rates from the primary surrogate country. Additionally, the Department determined that the best data source for industry-specific labor rates is Chapter 6A: Labor Cost in Manufacturing, from the International Labor Organization (ILO) Yearbook of Labor Statistics (''Yearbook'').

In these preliminary results, the Department has calculated the labor input using the wage method described in *Labor Methodologies.* To value the respondent's labor input, the Department relied on data reported by Thailand to the ILO in Chapter 6A of the Yearbook. Although the Department further finds the two-digit description under ISIC—Revision 3 (''Manufacture of furniture; manufacture of n.e.c.'') to be the best available information on the record because it is specific to the industry being examined, and is therefore derived from industries that produce comparable merchandise, Thailand has not reported data specific to the two-digit description since 2000. However, Thailand did report total manufacturing wage data in 2005. Accordingly, relying on Chapter 6A of the Yearbook, the Department calculated the labor input using total labor data reported by Thailand to the ILO, in accordance with section 773(c)(4) of the Act. For these preliminary results, the calculated industry-specific wage rate is 134.92 Baht/hour. A more detailed description of the wage rate calculation methodology is provided in the Surrogate Value Memorandum at page 5.

As stated above, the Department used Thailand ILO data reported under Chapter 6A of Yearbook, which reflects all costs related to labor, including wages, benefits, housing, training, etc. Additionally, where the financial statements used to calculate the surrogate financial ratios include itemized detail of labor costs, the Department made adjustments to certain labor costs in the surrogate financial ratios.[32]

We used Thai transport information in order to value the freight-in cost of the raw materials. To value inland truck freight, we obtained (1) August 2005 price data from the Thailand Board of Investment's 2006 publication, Costs of Doing Business in Thailand, and (2) distances from Google Maps, at *http://maps.google.com.* The Department calculated the per-kilometer price to transport one kg from Bangkok to five cities in Thailand. We inflated this value to the POR.

To value diesel, we used a per-liter value obtained from Thailand Board of Investment's Web page at *http://www.boi.go.th/index.php?page=transportation_costs_including_fuel_and_freight_rates,* effective August 30, 2011. We converted the source value in liters into the unit of measure reported by Feili and made adjustments to account for deflation.

To value electricity, we used the average price of Thai power suppliers, as published by Electricity Generating Authority of Thailand in ''2010 Annual Report: Key Statistical Data.'' We did not inflate this value because utility rates represent current rates, as indicated by the effective dates listed for each of the rates provided.[33] We valued water using data from Thailand's Board of Investment.[34] This source provides water rates for industrial users that are VAT exclusive.

For factory overhead, selling, general, and administrative expenses (''SG&A''), and profit values, we used the financial statements of Siam. We have not used the other two Thai financial statements on the record of this review because one is not contemporaneous to the POR, and the other does not provide sufficient detail for calculation of surrogate financial ratios. We find that Siam is the best available information with which to determine factory overhead as a percentage of the total raw materials, labor and energy (''ML&E'') costs; SG&A as a percentage of ML&E plus overhead (*i.e.,* cost of manufacture); and the profit rate as a percentage of the cost of manufacture plus SG&A.

For packing materials, we used the per-kilogram values obtained from the GTA and made adjustments to account for freight costs incurred between the PRC supplier and Feili's plants.[35]

[25] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 42672, 42682 (July 16, 2004), unchanged in *Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from the Socialist Republic of Vietnam,* 69 FR 71005 (December 8, 2004).

[26] *See* Prelim SV Memo at 2–3.

[27] *See, e.g., Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 74 FR 9591, 9600 (March 5, 2009), unchanged in *Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Final Determination of Sales at Less than Fair Value,* 74 FR 36656 (July 24, 2009).

[28] *See Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy Wages, Duty Drawback; and Request for Comments,* 71 FR 61716, 61717–19 (October 19, 2006) (''*Antidumping Methodologies: Market Economy Inputs''*).

[29] For a detailed description of all actual values used for market-economy inputs, *see* Preliminary Analysis Memorandum at 7.

[30] *See Antidumping Methodologies: Market Economy Inputs,* 71 FR at 61718.

[31] *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (''*Labor Methodologies''*).

[32] *See Labor Methodologies,* 76 FR at 36093.

[33] *See* Prelim SV Memo at 5 and Attachment VI.

[34] *See* Prelim SV Memo at 4 and Attachment VIII.

[35] *See* Prelim SV Memo.

Currency Conversion

We made currency conversions into U.S. dollars, where appropriate, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank.

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margin exists:

Exporter	Margin (percent)
Feili Group (Fujian) Co., Ltd./ Feili Furniture ..... Development Limited Quanzhou City.	36.45

Disclosure

We will disclose the calculations used in our analysis to parties to this proceeding within five days of the publication date of this notice.[36] Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments within 30 days of the date of publication of this notice.[37] Interested parties may file rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, no later than five days after the date on which the case briefs are due.[38] The Department requests that parties submitting written comments provide an executive summary and a table of authorities as well as an additional copy of those comments electronically.

Any interested party may request a hearing within 30 days of publication of this notice.[39] If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230.[40] The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Deadline for Submission of Publicly Available Surrogate Value Information

In accordance with 19 CFR 351.301(c)(3)(ii), the deadline for submission of publicly available information to value FOPs under 19 CFR 351.408(c) is 20 days after the date of publication of the preliminary results. In accordance with 19 CFR 351.301(c)(1), if an interested party submits factual information less than ten days before, on, or after (if the Department has extended the deadline), the applicable deadline for submission of such factual information, an interested party has ten days to submit factual information to rebut, clarify, or correct the factual information no later than ten days after such factual information is served on the interested party. However, the Department generally will not accept in the rebuttal submission additional or alternative SV information not previously on the record, if the deadline for submission of SV information has passed.[41] Furthermore, the Department generally will not accept business proprietary information in either the SV submissions or the rebuttals thereto, as the regulation regarding the submission of SVs allows only for the submission of publicly available information.[42]

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by the review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of the review. In accordance with 19 CFR 351.212(b)(1), we calculated exporter/importer (or customer)-specific assessment rates for the merchandise subject to the review.

Where the respondent reports reliable entered values, we calculate importer (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).[43] Where an importer (or customer)-specific *ad valorem* rate is greater than *de minimis,* we will apply the assessment rate to the entered value of the importers'/customers' entries during the POR.[44] Where we do not have entered values for all U.S. sales, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to each importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).

To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer (or customer)-specific *ad valorem* ratios based on the estimated entered value. Where an importer (or customer)-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[45]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of the administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For Feili, the cash deposit rate will be the company-specific rate established in the final results of the review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 70.71 percent; and (4) for all non-PRC exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

[36] *See* 19 CFR 351.224(b).

[37] *See* 19 CFR 351.309(c).

[38] *See* 19 CFR 351.309(d).

[39] *See* 19 CFR 351.310(c).

[40] *See* 19 CFR 351.310(d).

[41] *See, e.g., Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007), and accompanying Issues and Decision Memorandum at Comment 2.

[42] *See* 19 CFR 351.301(c)(3).

[43] *See* 19 CFR 351.212(b)(1).

[44] *See* 19 CFR 351.212(b)(1).

[45] *See* 19 CFR 351.106(c)(2).

Dated: March 1, 2012.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. 2012–5579 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Carbon and Certain Alloy Steel Wire Rod From Mexico: Notice of Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On November 1, 2011, the Department of Commerce (the Department) published in the **Federal Register** the preliminary results of the administrative review of the antidumping duty order on carbon and certain alloy steel wire rod (wire rod) from Mexico.[1] This review covers imports of wire rod from ArcelorMittal Las Truchas, S.A. de C.V. (AMLT) and its affiliate, ArcelorMittal International America LLC (AMIA).[2] The period of review (POR) is October 1, 2009, through September 30, 2010.

Based on our analysis of comments received, these final results differ from the preliminary results. The final results are listed below in the *Final Results* of Review section.

DATES: *Effective Date:* March 7, 2012.

FOR FURTHER INFORMATION CONTACT: Jolanta Lawska, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–8362.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2011, the Department published the *Preliminary Results* of the fifth administrative review of the antidumping duty order on wire rod from Mexico. *See Preliminary Results.* We invited interested parties to comment on the *Preliminary Results.* On December 1, 2011, the Department received case briefs from AMLT and petitioners, Nucor Corporation (Nucor) and Cascade Steel Rolling Mills, Inc. (Cascade Mills). On December 6, 2011, the Department received rebuttal briefs from Nucor and Cascade Mills, and ArcelorMittal USA Inc., (ArcelorMittal USA), Gerdau Ameristeel US Inc., (Gerdau), and Evraz Rocky Mountain Steel (Evraz Steel). No party requested a hearing.

Scope of the Order

The merchandise subject to this order is certain hot-rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.

Specifically excluded are steel products possessing the above-noted physical characteristics and meeting the Harmonized Tariff Schedule of the United States (HTSUS) definitions for (a) stainless steel; (b) tool steel; (c) high nickel steel; (d) ball bearing steel; and (e) concrete reinforcing bars and rods. Also excluded are (f) free machining steel products (*i.e.,* products that contain by weight one or more of the following elements: 0.03 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorus, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium).

Also excluded from the scope are 1080 grade tire cord quality wire rod and 1080 grade tire bead quality wire rod. This grade 1080 tire cord quality rod is defined as: (i) Grade 1080 tire cord quality wire rod measuring 5.0 mm or more but not more than 6.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non-deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.15 mm; (vi) capable of being drawn to a diameter of 0.30 mm or less with 3 or fewer breaks per ton, and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.006 percent or less of nitrogen, and (5) not more than 0.15 percent, in the aggregate, of copper, nickel and chromium.

This grade 1080 tire bead quality rod is defined as: (i) Grade 1080 tire bead quality wire rod measuring 5.5 mm or more but not more than 7.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non-deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.2 mm; (vi) capable of being drawn to a diameter of 0.78 mm or larger with 0.5 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of soluble aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.008 percent or less of nitrogen, and (5) either not more than 0.15 percent, in the aggregate, of copper, nickel and chromium (if chromium is not specified), or not more than 0.10 percent in the aggregate of copper and nickel and a chromium content of 0.24 to 0.30 percent (if chromium is specified).

For purposes of the grade 1080 tire cord quality wire rod and the grade 1080 tire bead quality wire rod, an inclusion will be considered to be deformable if its ratio of length (measured along the axis—that is, the direction of rolling—of the rod) over thickness (measured on the same inclusion in a direction perpendicular to the axis of the rod) is equal to or greater than three. The size of an inclusion for purposes of the 20 microns and 35 microns limitations is the measurement of the largest dimension observed on a longitudinal section measured in a direction perpendicular to the axis of the rod. This measurement methodology applies only to inclusions on certain grade 1080 tire cord quality wire rod and certain grade 1080 tire bead quality wire rod that are entered, or withdrawn from warehouse, for consumption on or after July 24, 2003.

The designation of the products as ''tire cord quality'' or ''tire bead quality'' indicates the acceptability of the product for use in the production of tire cord, tire bead, or wire for use in other rubber reinforcement applications such as hose wire. These quality designations are presumed to indicate that these products are being used in tire cord, tire bead, and other rubber reinforcement applications, and such merchandise

[1] *See Carbon and Certain Alloy Steel Wire Rod from Mexico: Notice of Preliminary Results of Antidumping Duty Administrative Review* 76 FR 67407 (November 1, 2011) (*Preliminary Results*).

[2] We determined that AMLT is the successor-in-interest to Sicartsa in an antidumping changed circumstances review. The final **Federal Register** notice was published on July 29, 2011. *See Final Results of Antidumping Duty Changed Circumstances Review: Carbon and Certain Alloy Steel Wire Rod from Mexico,* 76 FR 45509 (July 29, 2011).

intended for the tire cord, tire bead, or other rubber reinforcement applications is not included in the scope. However, should the petitioners or other interested parties provide a reasonable basis to believe or suspect that there exists a pattern of importation of such products for other than those applications, end-use certification for the importation of such products may be required. Under such circumstances, only the importers of record would normally be required to certify the end use of the imported merchandise.

All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products subject to this order are currently classifiable under subheadings 7213.91.3000, 7213.91.3010, 7213.91.3011, 7213.91.3015, 7213.91.3020, 7213.91.3090, 7213.91.3091, 7213.91.3092, 7213.91.3093, 7213.91.4500, 7213.91.4510, 7213.91.4590, 7213.91.6000, 7213.91.6010, 7213.91.6090, 7213.99.0030, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0000, 7227.20.0010, 7227.20.0020, 7227.20.0030, 7227.20.0080, 7227.20.0090, 7227.20.0095, 7227.90.6010, 7227.90.6020, 7227.90.6050, 7227.90.6051 7227.90.6053, 7227.90.6058, 7227.90.6059, 7227.90.6080, and 7227.90.6085 of the HTSUS.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this administrative review are addressed in the Issues and Decision Memorandum for the Final Results of the Fifth Administrative Review of the Antidumping Duty Order on Carbon and Certain Alloy Steel Wire Rod from Mexico from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Import Administration, (Decision Memorandum), dated concurrently with this notice and which is hereby adopted by this notice. A list of the issues which parties have raised, and to which we have responded in the Decision Memorandum, is attached to this notice as an Appendix. The Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available in the Central Records Unit, main Commerce Building, Room 7046. In addition, a complete version of the Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn/.* The signed Decision Memorandum and electronic version of the Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received for AMLT, we have recalculated AMLT's inland freight expenses incurred in the home market. We have applied an inland freight expense of zero for those home market transactions in which AMLT reported that no inland freight costs were incurred. For all other home market sales, we have continued to apply the partial adverse facts available (AFA) methodology utilized in the *Preliminary Results.* AMLT's adjustments are discussed in detail in the accompanying Decision Memorandum. *See* February 29, 2012, Final Calculation Memorandum for AMLT.

Final Results of Review

As a result of our review, we determine that the following weighted-average dumping margin exists for the period October 1, 2009, through September 30, 2010:

Producer/ Manufacturer	Weighted-Average margin (Percent)
AMLT	5.59

Assessment Rate

Pursuant to these final results, the Department has determined, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions for AMLT to CBP 15 days after the date of publication of these final results. Pursuant to 19 CFR 351.212(b)(1), we calculated importer-specific (or customer-specific) *ad valorem* duty assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific (or customer-specific) assessment rates calculated in the final results of this review are above *de minimis.*

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment of Antidumping Duties*). This clarification will apply to entries of subject merchandise during the POR produced by AMLT for which AMLT did not know the merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate un-reviewed entries at the all-others rate if there is no company-specific rate for an intermediary involved in the transaction. *See Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine,* 67 FR 65945, 65947 (October 29, 2002) (*Wire Rod Orders*) (establishing an all-others rate of 20.11 percent). *See Assessment of Antidumping Duties* for a full discussion of this clarification.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of wire rod from Mexico entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Tariff Act of 1930, as amended (the Act): (1) The cash deposit rate for AMLT will be the rate established in the final results of review; (2) if the exporter is not a firm covered in this review or the less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (3) if neither the exporter nor the manufacturer is a firm covered in this or any previous review conducted by the Department, the cash deposit rate will be 20.11 percent, the all-others rate established in the LTFV investigation. *See Wire Rod Orders* at 65947. These deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties. *See* 19 CFR 351.402(f)(3).

Notification to Interested Parties

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their

responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These final results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: February 29, 2012.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

Appendix

List of Comments:

ArcelorMittal Las Truchas, S.A. de C.V. (AMLT)

Comment 1: Treatment of Sales with Negative Dumping Margins (Zeroing)
Comment 2: Application of Partial Adverse Facts Available to ArcelorMittal Las Truchas, S.A. de C.V.'s Reported Home Market Inland Freight Expenses

[FR Doc. 2012–5575 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results of Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is conducting the sixth administrative review of the antidumping duty order on certain frozen warmwater shrimp (''shrimp'') from the Socialist Republic of Vietnam (''Vietnam'') for the period of review (''POR'') February 1, 2010, through January 31, 2011. As discussed below, we preliminarily determine that sales have been made below normal value (''NV''). If these preliminary results are adopted in our final results of review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on entries of subject merchandise during the POR for which the importer-specific assessment rates are above *de minimis.*

DATES: *Effective Date:* March 7, 2012.

FOR FURTHER INFORMATION CONTACT: Toni Dach or Seth Isenberg, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1655 or (202) 482–0588, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 1, 2005, the Department published in the **Federal Register** the antidumping duty order on frozen warmwater shrimp from Vietnam.[1] On February 1, 2011, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the period February 1, 2010, through January 31, 2011.[2]

From February 25, 2011, through February 28, 2011, we received requests to conduct administrative reviews from the American Shrimp Processors Association (''ASPA''), the Domestic Producers,[3] and certain Vietnamese companies. On March 31, 2011, the Department published in the **Federal Register** the notice of initiation of this administrative review.[4]

On October 20, 2011, the Department published in the **Federal Register** a notice extending the time period for issuing the preliminary results by 90 days.[5] On January 20, 2012, the Department published in the **Federal Register** an additional notice extending the time period for issuing the preliminary results by 30 days.[6]

On May 15, 2011, the Department received a letter from Quoc Viet Seaproducts Processing Trading Import and Export Co., Ltd. (''Quoc Viet'') indicating that it made no shipments of subject merchandise during the POR. On May 31, 2011, the Department received similar letters from Nam Hai Foodstuff and Export Company Ltd. (''Nam Hai'') and Vinh Loi Import Export Company (''Vinh Loi''). Of the 68 companies/groups upon which we initiated an administrative review, 24 companies submitted separate-rate certifications, 10 companies submitted separate-rate applications, and three companies stated that they did not export subject merchandise to the United States during the POR.

Respondent Selection

Section 777A(c)(1) of the Tariff Act of 1930, as amended (''the Act''), directs the Department to calculate individual dumping margins for each known exporter or producer of the subject merchandise.[7] However, section 777A(c)(2) of the Act gives the Department the discretion to limit its examination to a reasonable number of exporters or producers if it is not practicable to examine all exporters or producers involved in an administrative review.

On April 19, 2011, the Department released CBP data for entries of subject merchandise during the POR under administrative protective order (''APO'') to all interested parties having an APO as of the date of this release, and invited comments regarding the CBP data and respondent selection. On April 29, 2011, the Department received comments from the ASPA, the Domestic Producers, and certain Vietnamese respondents regarding respondent selection for this review. No other interested parties submitted comments for respondent selection and no interested parties rebutted these respondent selection comments.

On June 17, 2011, the Department issued the respondent selection memorandum, in which it explained that, because of the large numbers of exporters or producers involved in the review, it would not be practicable to individually examine all companies. Rather, the Department determined that it could only reasonably examine two exporters in this review. Pursuant to section 777A(c)(2)(B) of the Act, the Department selected Minh Phu Seafood Corporation (and its affiliates Minh Qui Seafood Co., Ltd., and Minh Phat Seafood Co., Ltd.) (collectively ''the Minh Phu Group''), and Nha Trang Seaproduct Company (''Nha Trang

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam,* 70 FR 5152 (February 1, 2005) (''*Order*'').

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 76 FR 5559 (February 1, 2011).

[3] The Domestic Producers are the Ad Hoc Shrimp Trade Action Committee members: Nancy Edens; Papa Rod, Inc.; Carolina Seafoods; Bosarge Boats, Inc.; Knight's Seafood Inc.; Big Grapes, Inc.; Versaggi Shrimp Co.; and Craig Wallis.

[4] *See Initiation of Antidumping Duty Administrative Reviews, Requests for Revocation in Part, and Deferral of Administrative Review,* 76 FR 17825 (March 31, 2011).

[5] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Extension of Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 65178 (October 20, 2011).

[6] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Extension of Preliminary Results of Antidumping Duty Administrative Review,* 77 FR 2958 (January 20, 2012).

[7] *See also* 19 CFR 351.204(c) regarding respondent selection, in general.

Seafoods'').[8] The Department issued the non-market economy (''NME'') antidumping questionnaire to the Minh Phu Group and Nha Trang Seafoods on June 20, 2011. Responses from both companies were received in July and August, 2011. The Department issued supplemental questionnaires in November, 2011 and responses were received in December, 2011.

Period of Review

The POR is February 1, 2010, through January 31, 2011.

Scope of the Order

The scope of the order includes certain frozen warmwater shrimp and prawns, whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off,[9] deveined or not deveined, cooked or raw, or otherwise processed in frozen form.

The frozen warmwater shrimp and prawn products included in the scope of the order, regardless of definitions in the Harmonized Tariff Schedule of the United States (''HTSUS''), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the *Penaeidae* family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannemei*), banana prawn (*Penaeus merguiensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope of the order. In addition, food preparations, which are not ''prepared meals,'' that contain more than 20 percent by weight of shrimp or prawn are also included in the scope of the order.

Excluded from the scope are: (1) Breaded shrimp and prawns (HTS subheading 1605.20.10.20); (2) shrimp and prawns generally classified in the *Pandalidae* family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTS subheadings 0306.23.00.20 and 0306.23.00.40); (4) shrimp and prawns in prepared meals (HTS subheading 1605.20.05.10); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTS subheading 1605.20.10.40); (7) certain dusted shrimp; [10] and (8) certain battered shrimp. Dusted shrimp is a shrimp-based product: (1) That is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a ''dusting'' layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and 10 percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to IQF freezing immediately after application of the dusting layer. Battered shrimp is a shrimp-based product that, when dusted in accordance with the definition of dusting above, is coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the order are currently classified under the following HTSUS subheadings: 0306.13.00.03, 0306.13.00.06, 0306.13.00.09, 0306.13.00.12, 0306.13.00.15, 0306.13.00.18, 0306.13.00.21, 0306.13.00.24, 0306.13.00.27, 0306.13.00.40, 1605.20.10.10 and 1605.20.10.30. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope of the order is dispositive.

Preliminary Partial Rescission of Administrative Review

Between May 15 and May 31, 2011, Quoc Viet, Nam Hai and Vinh Loi filed no shipment certifications indicating that they did not export subject merchandise to the United States during the POR. In order to examine these claims, we sent an inquiry to CBP requesting that any CBP office that had any information contrary to the no shipments claims, to alert the Department. We have received no such response from CBP.

Therefore, pursuant to 19 CFR 351.213(d)(3), we preliminarily determine that the above-referenced companies made no shipments of subject merchandise during the POR, and we are preliminarily rescinding the review with respect to them.[11]

Additionally, we note that Thong Thuan Company Limited (''Thong Thuan'') is currently under review in the 2010–2011 new shipper review of certain frozen warmwater shrimp from Vietnam.[12] All entries made by Thong Thuan during the POR are under review in that segment.[13] Therefore, the Department is preliminarily rescinding this administrative review with respect to Thong Thuan, as it has no additional entries to be reviewed in this segment.

Withdrawal of Request for Administrative Review

On May 20, 2011, the Domestic Producers withdrew their request for review of Bim Seafood Joint Stock Company (''Bim Seafood''). Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. Therefore, as the withdrawal of the request for review of

[8] *See* Memorandum to James Doyle, Director, AD/CVD Operations, Office 9, from Toni Dach, International Trade Compliance Analyst, Office 9; 6th Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Selection of Respondents for Individual Review, dated June 17, 2011.

[9] ''Tails'' in this context means the tail fan, which includes the telson and the uropods.

[10] On April 26, 2011, the Department amended the antidumping duty order to include dusted shrimp, pursuant to the U.S. Court of International Trade (''CIT'') decision in *Ad Hoc Shrimp Trade Action Committee* v. *United States,* 703 F. Supp. 2d 1330 (CIT 2010) and the U.S. International Trade Commission (''ITC'') determination, which found the domestic like product to include dusted shrimp. Because the amendment of the antidumping duty order occurred after this POR, dusted shrimp continue to be excluded in this review. *See Certain Frozen Warmwater Shrimp From Brazil, India, the People's Republic of China, Thailand, and the Socialist Republic of Vietnam: Amended Antidumping Duty Orders in Accordance with Final Court Decision,* 76 FR 23227 (April 26, 2011); *see also, Ad Hoc Shrimp Trade Action Committee* v. *United States,* 703 F. Supp. 2d 1330 (CIT 2010) and *Frozen Warmwater Shrimp from Brazil, China, India, Thailand, and Vietnam (Investigation Nos. 731–TA–1063, 1064, 1066–1068 (Review),* USITC Publication 4221, March 2011.

[11] *See, e.g., Fourth Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Preliminary Results, Preliminary Partial Rescission of Antidumping Duty Administrative Review and Intent Not To Revoke, In Part,* 75 FR 11855, 11856–57 (March 12, 2010) (unchanged in final results).

[12] On June 13, 2011, the Department held consultations with counsel for Thong Thuan, in which they indicated that Thong Thuan wished to pursue the New Shipper Review, despite Thong Thuan's request for an Administrative Review.

[13] *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty New Shipper Review,* 77 FR 1053 (January 9, 2012).

Bim Seafood was timely, we are preliminarily rescinding this review with respect to Bim Seafood.

Collapsing

As indicated above, the Department selected the Minh Phu Group as one of the mandatory respondents in this review. In responding to the Department's antidumping questionnaire, the Minh Phu Group requested that the Department collapse an affiliated producer, Minh Phu Hau Giang Seafood Co., Ltd. (''Hau Giang''), with the Minh Phu Group. The Minh Phu Group based its request to collapse Hau Giang with itself primarily on the fact that the Minh Phu Group is a significant shareholder in Hau Giang and Hau Giang is controlled by the Minh Phu Group through shared management.

Pursuant to 19 CFR 351.401(f), the Department will collapse producers and treat them as a single entity where: (1) Those producers are affiliated, (2) the producers have production facilities for producing similar or identical products that would not require substantial retooling of either facility in order to restructure manufacturing priorities, and (3) there is a significant potential for manipulation of price or production.

To the extent that this provision does not conflict with the Department's application of separate rates and enforcement of the non-market economy (''NME'') provision, section 773(c) of the Act, the Department will collapse two or more affiliated entities in a case involving an NME country if the facts of the case warrant such treatment. Furthermore, we note the factors listed in 19 CFR 351.401(f)(2) are not exhaustive, and in the context of an NME investigation or administrative review, other factors unique to the relationship of business entities within the NME country may lead the Department to determine that collapsing is either warranted or unwarranted, depending on the facts of the case.[14]

In summary, if there is evidence of significant potential for manipulation between or among affiliates which produce and/or export similar or identical merchandise, whether or not all such merchandise is exported to the United States, the Department may find such evidence sufficient to apply the collapsing criteria in an NME context in order to determine whether all or some of those affiliates should be treated as one entity.[15]

The decision of whether to collapse two or more affiliated companies is specific to the facts presented in the proceeding and is based on several considerations, including the structure of the collapsed entity, the level of control between and among affiliates, and the level of participation by each affiliate in the proceeding. Given the unique relationships which arise in NMEs between individual companies and the government, the same separate rate will be assigned to each individual company that is part of the collapsed entity only if the facts, taken as a whole, support such a finding.[16]

Based on the reasons explained in the Collapsing Memo, and pursuant to 19 CFR 351.401(f), we have preliminarily collapsed Hau Giang and the Minh Phu Group.[17] All subsequent references in this notice to the Minh Phu Group will be to the collapsed entity that includes the Minh Phu Group and Hau Giang.

Surrogate Country and Surrogate Value Data

On July 20, 2011, the Department sent interested parties a letter inviting comments on surrogate country selection and information regarding valuing factors of production (''FOPs''). On September 12, 2011, the ASPA, the Domestic Producers, and certain Vietnamese respondents filed comments on surrogate country selection, stating India, the Philippines, and Bangladesh may be appropriate surrogates if their data are publicly available, reliable and contemporaneous. On December 12, 2011, the Department received information to value FOPs from the ASPA, the Domestic Producers, and certain Vietnamese respondents. The ASPA provided certain surrogate values from sources in India, the Domestic Producers provided surrogate values from sources in the Philippines, and the Vietnamese respondents provided surrogate values from sources in Bangladesh and Indonesia.

Surrogate Country

When the Department investigates imports from an NME country and available information does not permit the Department to determine NV pursuant to section 773(a) of the Act, then, pursuant to sections 773(c)(1) and 773(c)(4) of the Act, the Department bases NV on an NME producer's FOPs, to the extent possible, in one or more market-economy countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. Regarding the ''level of economic development,'' the Department relied on per capita gross national income (''GNI'') data to measure economic comparability.[18] Further, pursuant to 19 CFR 351.408(c)(2), the Department will normally value FOPs in a single country. The sources of the surrogate factor values are discussed under the ''Normal Value'' section below and in the Memorandum to the File through Scot Fullerton, Program Manager, Office 9 from Toni Dach, Senior International Trade Analyst, Office 9: Sixth Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Surrogate Values for the Preliminary Results, dated February 28, 2012 (''Surrogate Value Memorandum'').

Pursuant to its practice, the Department received a list of potential surrogate countries from Import Administration's Office of Policy (''OP'').[19] The OP determined that Bangladesh, Ghana, India, Indonesia, Nicaragua, and the Philippines were at

[14] *See Hontex Enterprises, Inc.* v. *United States,* 248 F. Supp. 2d 1323, 1342 (CIT 2003) (noting that the application of collapsing in the NME context may differ from the standard factors listed in the regulation).

[15] *See Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products From the People's Republic of China,* 66 FR 22183 (May 3, 2001); *Final Determination of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products From the People's Republic of China,* 66 FR 49632 (September 28, 2001); and *Anshan Iron & Steel Co., Ltd.* v. *United States,* 27 C.I.T. 1234, 1246–47 (CIT 2003).

[16] *See* ''Separate Rates'' section below for further discussion.

[17] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, through James Doyle, Director, Office 9, AD/CVD Operations, from Toni Dach, Senior International Trade Analyst, Office 9, AD/CVD Operations, Regarding Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Whether to Collapse Minh Phu Hau Giang Seafood Co., Ltd. and the Minh Phu Group, dated February 28, 2012 (''Collapsing Memo'').

[18] Although 19 CFR 351.408(b) instructs the Department to rely on gross domestic product (''GDP'') data in such comparisons, it is Departmental practice to use ''per capita GNI, rather than per capita GDP, because while the two measures are very similar, per capita GNI is reported across almost all countries by an authoritative source (the World Bank), and because the Department finds that the per capita GNI represents the single best measure of a country's level of total income and thus level of economic development.'' *See Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy Wages, Duty Drawback; and Request for Comments,* 71 FR 61716 (October 19, 2006).

[19] *See* Memorandum from Carole Showers, Director, Office of Policy, to Scot T. Fullerton, Program Manager, AD/CVD Operations, Office 9: Request for a List of Surrogate Countries for an Antidumping Duty Administrative Review of the Antidumping Duty Order on Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam, dated July 20, 2011 (''Surrogate Country List'').

a comparable level of economic development to Vietnam.[20] The Department considers the six countries identified by the OP in its Surrogate Country List as ''equally comparable in terms of economic development.'' [21] Thus, we find Bangladesh, Ghana, India, Indonesia, Nicaragua, and the Philippines are all at an economic level of development equally comparable to that of Vietnam. We note that the Surrogate Country List is a non-exhaustive list of economically comparable countries. We also note that the record does not contain publicly available SV factor information for Ghana, Nicaragua, or Indonesia. Parties submitted information demonstrating that Bangladesh, India, and the Philippines are significant producers of subject merchandise.[22] Thus, we find that Bangladesh, India, and the Philippines are economically comparable to Vietnam and significant producers of the subject merchandise.

Once we have identified the countries that are economically comparable to Vietnam and are significant producers of the subject merchandise, we select an appropriate surrogate country by determining whether the data for valuing FOPs are both available and reliable.

Regarding the Bangladeshi data, the record contains publicly available surrogate factor value information for most FOPs. With respect to the main raw material input, shrimp, the Vietnamese respondents provided data for Bangladesh from a study conducted by the Network of Aquaculture Centres in Asia-Pacific (''NACA''), an intergovernmental organization affiliated with the United Nation's (''UN'') Food and Agricultural Organization (''FAO'').

With respect to India, the record contains publicly available surrogate value information for some FOPs. Although the ASPA noted in its December 12, 2011, surrogate value submission that it would place publicly available information from India to value shrimp on the record, no information from India to value shrimp has been placed on the record.

With regard to the Philippines, the record contains publicly available surrogate factor value information for all FOPs. Domestic Producers provided shrimp data for the Philippines published by the Philippines Fisheries Development Authority (''PFDA'') at Navotas City Fish Port.

The Department's practice when selecting the best available information for valuing FOPs, in accordance with section 773(c)(1) of the Act, is to select, to the extent practicable, SVs which are product-specific, representative of a broad-market average, publicly available, contemporaneous with the POR and exclusive of taxes and duties.[23] As a general matter, the Department prefers to use publicly available data representing a broad-market average to value SVs.[24] The Department notes that the value of the main input, head-on, shell-on shrimp, is a critical FOP in the dumping calculation as it accounts for a significant percentage of NV. Moreover, the ability to value shrimp on a count-size basis is a significant consideration with respect to the data available on the record, as the subject merchandise and the raw shrimp input are both sold on a count-size specific basis. For these reasons, in prior administrative reviews, the Department rejected shrimp SVs with limited count sizes.[25]

The Bangladeshi shrimp values within the NACA study are compiled by the UN's FAO from actual pricing records kept by Bangladeshi farmers, traders, depots, agents, and processors.[26] The Bangladeshi shrimp values within the NACA study are publicly available, represent a broad-market average, are product-specific, count-size-specific, contemporaneous and represent actual transaction prices. Unlike the Bangladeshi data within the NACA study, the Philippine shrimp data is limited and does not satisfy as many factors of the Department's data selection criteria. Specifically, we note that the PFDA data contains limited count-size specific data, omitting substantial portions of the range of sizes of shrimp sold by the respondents. Therefore, with respect to the data considerations, we find that the record contains shrimp values for Bangladesh that better meet our selection criteria than the Philippine source. Moreover, there is no shrimp value information from India on the record of this review. Accordingly, as shrimp is the main factor of production in this case, we have selected Bangladesh as the primary surrogate country as the shrimp surrogate value for Bangladesh is the most specific to the input consumed.

In this regard, given the above-cited facts, we find that the information on the record shows that Bangladesh is an appropriate surrogate country because Bangladesh is at a similar level of economic development pursuant to section 773(c)(4) of the Act, is a significant producer of comparable merchandise, and has reliable, publicly available data for surrogate valuation purposes, particularly for the main factor of production, *i.e.,* shrimp.

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results in an antidumping administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results.

Verification

Pursuant to 19 CFR 351.307(b)(iv), between January 16 and January 20, 2012, the Department conducted a verification of Nha Trang Seafoods' sales and FOPs.[27]

Non-Market Economy Country Status

In every case conducted by the Department involving Vietnam, Vietnam has been treated as an NME country. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority.[28] None of the parties to this proceeding have contested such treatment. Accordingly, we calculated the NV in accordance with section 773(c) of the Act, which applies to NME countries.

Separate Rates

In NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single

[20] *Id.*

[21] *Id.*

[22] *See* September 12, 2011, submissions from the ASPA, Domestic Producers, and Certain Vietnamese Respondents.

[23] *See Fresh Garlic from the People's Republic of China: Final Results and Partial Rescission of the Eleventh Administrative Review and New Shipper Reviews,* 72 FR 34438 (June 22, 2007) and accompanying Issues and Decision Memorandum at Comment 2A.

[24] *Id.*

[25] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 74 FR 47191 (September 15, 2009) and accompanying Issues and Decision Memorandum at Comment 6.

[26] *See* Surrogate Value Memorandum.

[27] *See* Memorandum to the File through Scot Fullerton, Program Manager, Office 9, from Toni Dach, Senior International Trade Analyst, and Seth Isenberg, International Trade Analyst, ''Verification of the Sales and Factors of Production Response Nha Trang Seaproduct Group in the 2010–11 Administrative Review of Certain Warmwater Shrimp from the Socialist Republic of Vietnam,'' dated February 28, 2012.

[28] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results, Partial Rescission and Request for Revocation, in Part, of the Fourth Administrative Review,* 75 FR 12206 (March 15, 2010) (unchanged in final results).

antidumping duty rate.[29] However, a company in the NME applying for separate rate status may rebut that presumption by demonstrating an absence of both *de jure* and *de facto* government control over its export activities.[30]

The Department analyzes each entity's export independence under a test first articulated in *Sparklers* and as further developed in *Silicon Carbide*.[31] Importantly, if the Department determines that a company is wholly foreign-owned or located in a market economy (''ME'') country, then the Department need not conduct a separate rate analysis to determine whether the company is independent from government control.[32]

In addition to the two mandatory respondents, the Minh Phu Group and Nha Trang Seafoods, the Department received separate rate applications or certifications from the following thirty-one companies (''Separate-Rate Applicants''):

1. Amanda Foods (Vietnam) Limited
2. Bac Lieu Fisheries Joint Stock Company
3. C.P. Vietnam Livestock Corporation
4. Cafatex Fishery Joint Stock Corporation, aka Cafatex Corp.
5. Cadovimex Seafood Import-Export and Processing Joint Stock Company, aka CADOVIMEX–VIETNAM
6. Ca Mau Seafood Joint Stock Company, aka Seaprimexco Vietnam
7. Camau Frozen Seafood Processing Import Export Corp.
8. Camranh Seafoods and Branch of Cam Ranh
9. Can Tho Import Export Fishery Limited Company, aka CAFISH
10. CATACO Sole Member Limited Liability Company, aka CATACO
11. Coastal Fisheries Development Corporation, aka COFIDEX
12. Cuulong Seaproducts Company, aka Cuulong Seapro
13. Danang Seaproducts Import Export Corporation, aka Seaprodex Danang and its branch Tho Quang Seafood Processing and Export Company
14. Viet I-Mei Frozen Foods Co., Ltd.
15. Gallant Ocean (Vietnam) Co. Ltd.
16. Investment Commerce Fisheries Corporation, aka INCOMFISH
17. Kim Anh Company, Limited
18. Minh Hai Export Frozen Seafood Processing Joint Stock Company, aka Minh Hai Jostoco
19. Minh Hai Joint-Stock Seafoods Processing Company, aka Seaprodex Minh Hai
20. Ngoc Sinh Private Enterprise and its branch, Ngoc Sinh Seafoods Processing and Trading Enterprise, aka Ngoc Sinh Seafoods
21. Ngoc Tri Seafood Joint Stock Company
22. Nhat Dhuc Co., Ltd.
23. Nha Trang Fisheries Joint Stock Company, aka Nha Trang Fisco
24. Phu Cuong Jostoco Seafood Corporation
25. Phuong Nam Foodstuff Corp., aka Phuong Nam Co., Ltd.
26. Sao Ta Foods Joint Stock Company, aka FIMEX VN
27. Soc Trang Seafood Joint Stock Company, aka STAPIMEX
28. Thuan Phuoc Seafoods and Trading Corporation
29. UTXI Aquatic Products Corporation, aka UTXICO
30. Vietnam Clean Seafood Corporation, aka VINA Cleanfood
31. Viet Hai Seafood Co., Ltd., a/k/a Vietnam Fish One Co., Ltd.

The status of the Separate-Rate Applicants is discussed below.

Thirty companies did not submit either a separate-rate application or certification.[33] Therefore, because these companies did not demonstrate their eligibility for separate rate status, they remain preliminarily included as part of the Vietnam-wide entity.

a. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies.[34] The evidence provided by the Minh Phu Group, Nha Trang Seafoods, and the Separate-Rate Applicants supports a preliminary finding of *de jure* absence of government control based on the following: (1) An absence of restrictive stipulations associated with the individual exporter's business and export licenses; (2) there are applicable legislative enactments decentralizing control of the companies; and (3) there are formal measures by the government decentralizing control of companies. *See, e.g.,* the Minh Phu Group's AQR at Exhibit 1, Nha Trang Seafoods Group's AQR at Exhibit A–1.

b. Absence of De Facto Control

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses.[35] The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The evidence provided by the Minh Phu Group, Nha Trang Seafoods, and the Separate-Rate Applicants supports a preliminary finding of *de facto* absence of government control based on the following: (1) The companies set their own export prices independent of the government and without the approval of a government authority; (2) the companies have authority to negotiate and sign contracts and other agreements; (3) the companies have autonomy from the government in making decisions regarding the selection of management; and (4) there is no restriction on any of the companies' use of export revenue. *See, e.g.,* the Minh Phu Group's AQR at 3–26 and Exhibit A–1, Nha Trang Seafoods

[29] *See Separate Rates and Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,* 70 FR 17233, 17233 (April 5, 2005) (''*Policy Bulletin 05.1*''), also available at: *http://ia.ita.doc.gov/policy/index.html; see also Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079, 53082 (September 8, 2006); and *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China,* 71 FR 29303, 29307 (May 22, 2006).

[30] *See Policy Bulletin 05.1.*

[31] *See Notice of Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588, 20589 (May 6, 1991) (''*Sparklers*''); *see also Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585, 22586–87 (May 2, 1994) (''*Silicon Carbide*'').

[32] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[33] *See* Appendix 1.

[34] *See Sparklers,* 56 FR at 20589.

[35] *See Silicon Carbide,* 59 FR at 22586–87; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995).

Group's AQR at 3–16 and Exhibit A–1. Therefore, the Department preliminarily finds that the Minh Phu Group, Nha Trang Seafoods, and the Separate-Rate Applicants have established that they qualify for a separate rate under the criteria established by *Silicon Carbide* and *Sparklers.*

Separate Rate Calculation

In the ''Respondent Selection'' section above, we stated that the Department employed a limited examination methodology, as it did not have the resources to examine all companies for which a review request was made, and selected two exporters as mandatory respondents in this review. The Minh Phu Group and Nha Trang Seafoods participated in the review as mandatory respondents. Thirty-three additional companies (listed in the ''Separate Rates'' section above) submitted timely information as requested by the Department and remained subject to review as separate rate respondents.

We note that the statute and the Department's regulations do not directly address the establishment of a rate to be applied to individual companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. The Department's practice in cases involving limited selection based on exporters accounting for the largest volumes of trade has been to look for guidance in section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Consequently, the Department generally weight-averages the rates calculated for the mandatory respondents, excluding zero and *de minimis* rates and rates based entirely on facts available (''FA''), and applies that resulting weighted-average margin to non-selected cooperative separate-rate respondents.[36]

However, the Department has, for these preliminary results, calculated a zero or *de minimis* dumping margin for the two mandatory respondents, the Minh Phu Group and Nha Trang Seafoods. In this circumstance, we again look to section 735(c)(5) of the Act for guidance. Section 735(c)(5)(A) of the Act instructs that we are not to calculate an all-others rate using any zero or *de minimis* margins or any margins based entirely on FA. Section 735(c)(5)(B) of the Act also provides that, where all margins are zero rates, *de minimis* rates, or rates based entirely on FA, we may use ''any reasonable method'' for assigning the rate to non-selected respondents. Therefore, because all rates in this proceeding are *de minimis,* we must look to other reasonable means to assign separate rate margins to non-reviewed companies eligible for a separate rate in this review. Given that the Department has calculated positive rates for mandatory respondents in the immediately preceding two administrative reviews,[37] distinguishing this review from the second and third reviews,[38] we find that a reasonable method is to assign to non-reviewed companies in this review the most recent calculated rate from a prior completed segment of the proceeding that is not zero or *de minimis,* and not based entirely on facts available (or average of such rates), or, if any non-selected company has its own calculated (non-adverse facts available) rate that is contemporaneous with or more recent than this rate, then the company will receive that rate. Pursuant to this method, we are assigning the rate of 1.03 percent, the most recent positive rate (from the amended final results of the fifth administrative review) calculated for cooperative separate rate respondents, to those separate rate respondents in the instant review.[39] However, for Camimex, who received a calculated rate in the fifth administrative review, we are assigning that calculated rate as the company's separate rate in this review. Therefore, for Camimex, we are assigning its most recently calculated rate (0.80 percent) as its separate rate in the instant review because this rate is contemporaneous with the separate rate calculated in the fifth administrative review and is based on the company's own data. We invite parties to provide comments on this methodology in their case briefs.

Vietnam-Wide Entity

Upon initiation of the administrative review, we provided the opportunity for all companies upon which the review was initiated to complete either the separate-rates application or certification. The separate-rate certification and separate-rate applications were available at: *http://ia.ita.doc.gov/nme/nme-sep-rate.html.*

We have preliminarily determined that 30 companies did not demonstrate their eligibility for a separate rate and are properly considered part of the Vietnam-wide entity. In NME proceedings, '''rates' may consist of a single dumping margin applicable to all exporters and producers.''[40] As explained above in the ''Separate Rates'' section, all companies within Vietnam are considered to be subject to government control unless they are able to demonstrate an absence of government control with respect to their export activities. Such companies are thus assigned a single antidumping duty rate distinct from the separate rate(s) determined for companies that are found to be independent of government control with respect to their export activities. We consider the influence that the government has been found to have over the economy to warrant determining a rate for the entity that is distinct from the rates found for companies that have provided sufficient evidence to establish that they operate freely with respect to their export activities.[41] In this regard, we note that no party has submitted evidence of the proceeding to demonstrate that such government influence is no longer present or that our treatment of the NME entity is otherwise incorrect. Therefore, we are assigning the entity a rate of 25.76%, the only rate ever determined for the Vietnam-wide entity in this proceeding.

Date of Sale

In accordance with 19 CFR 351.401(i) and the Department's long-standing practice of determining the date of sale,[42] the Department preliminarily determines that the invoice date is the most appropriate date to use as the Minh Phu Group and Nha Trang Seafoods date of sale. The Minh Phu Group and Nha Trang Seafoods reported the invoice date as the date of sale because they claim that, for their U.S. sales of subject merchandise made during the POR, the material terms of

[36] *See, e.g., Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Results of New Shipper Review and Partial Rescission of Administrative Review,* 73 FR 8273 (February 13, 2008) (unchanged in final results).

[37] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Amended Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 64307 (October 18, 2011) (''*Fifth Review Amended Final*'') and *Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Amended Final Results of Antidumping Duty Administrative Review,* 75 FR 61122 (October 4, 2010).

[38] *See Amanda Foods (Vietnam) Ltd* v. *United States,* 774 F.Supp.2d 1286 (CIT 2011); *Amanda Foods (Vietnam) Ltd* v. *United States,* 807 F.Supp.2d 1332 (CIT 2011).

[39] *See Fifth Review Amended Final.*

[40] *See* 19 CFR 351.107(d).

[41] *See Notice of Final Antidumping Duty Determination of Sales at Less Than Fair Value and Affirmative Critical Circumstances: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 68 FR 37116 (June 23, 2003).

[42] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Frozen and Canned Warmwater Shrimp From Thailand,* 69 FR 76918 (December 23, 2004), and accompanying Issues and Decision Memorandum at Comment 10.

sale were established based on the invoice date.

Fair Value Comparisons

To determine whether sales of shrimp to the United States by the Minh Phu Group and Nha Trang Seafoods were made at less than NV, the Department compared either export price (''EP'') or constructed export price (''CEP'') to NV, as described in the ''U.S. Price'' and ''Normal Value'' sections below.

U.S. Price

Export Price

In accordance with section 772(a) of the Act, the Department calculated EP for sales to the United States for Nha Trang Seafoods and a portion of sales to the United States for the Minh Phu Group because the first sale to an unaffiliated party was made before the date of importation and the use of CEP was not otherwise warranted. The Department calculated EP based on the sales price to unaffiliated purchasers in the United States. In accordance with section 772(c)(2)(A) of the Act, as appropriate, the Department deducted from the sales price certain foreign inland freight, brokerage and handling (''B&H''), and international movement costs. Because the inland freight and B&H services were either provided by a NME vendor or paid for using a NME currency, the Department based the deduction of these charges on surrogate values.[43] For international freight provided by a ME provider and paid in U.S. dollars, the Department used the actual cost per kilogram (''kg'') of the freight.

Constructed Export Price

For some of the Minh Phu Group's sales, the Department based U.S. price on CEP in accordance with section 772(b) of the Act, because sales were made on behalf of the Vietnam-based company by a U.S. affiliate to unaffiliated purchasers in the United States. For these sales, the Department based CEP on prices to the first unaffiliated purchaser in the United States. Where appropriate, the Department made deductions from the starting price (gross unit price) for foreign movement expenses, international movement expenses, U.S. movement expenses, and appropriate selling adjustments, in accordance with section 772(c)(2)(A) of the Act.

In accordance with section 772(d)(1) of the Act, the Department also deducted those selling expenses associated with economic activities occurring in the United States. The Department deducted, where appropriate, commissions, inventory carrying costs, interest revenue, credit expenses, warranty expenses, and indirect selling expenses. Where foreign movement expenses, international movement expenses, or U.S. movement expenses were provided by NME service providers or paid for in an NME currency, the Department valued these services using SVs (*see* ''Factor Valuations'' section below for further discussion). For those expenses that were provided by an ME provider and paid for in an ME currency, the Department used the reported expense. Due to the proprietary nature of certain adjustments to U.S. price, for a detailed description of all adjustments made to U.S. price for each company, *see* the company-specific analysis memoranda, dated concurrently with these preliminary results.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. Further, pursuant to section 773(c)(1) of the Act, the valuation of an NME respondent's FOPs shall be based on the best available information regarding the value of such factors in an ME country or countries considered to be appropriate by the Department. The Department bases NV on the FOPs because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.

The Department used import statistics into Bangladesh to value the raw material and packing material inputs that the Minh Phu Group and Nha Trang Seafoods used to produce the subject merchandise during the POR, except where listed below.

With respect to the SVs based on Bangladeshi import statistics, in according with the Omnibus Trade and Competitiveness Act of 1988 (''OTCA'') and long-standing agency practice, the Department has disregarded prices that the Department has reason to believe or suspect may be subsidized.[44] The Department has previously found that it is appropriate to disregard such prices from Indonesia, South Korea, and Thailand because we have determined that these countries maintain broadly available, non-industry specific, export subsidies.[45] Based on the existence of these subsidy programs that were generally available to all exporters and producers in these countries at the time of the POR, the Department finds that it has reason to believe or suspect that all exporters from Indonesia, South Korea, and Thailand may have benefitted from these subsidies and that we should therefore disregard any data from these countries contained in the Bangladeshi import statistics used to calculate SVs. The Department similarly disregarded prices from NME countries. Imports that were labeled as originating from an ''unspecified'' country were excluded from the average value, since the Department could not be certain that they were not from either an NME country or a country with generally available export subsidies.[46] Finally, the Department has excluded some imports identified as originating from Bangladesh.[47] For further discussion regarding all SV calculations using Bangladeshi Import Statistics, *see* Surrogate Value Memorandum.

Factor Valuations

In accordance with section 773(c)(1) of the Act, for subject merchandise produced by the Minh Phu Group and Nha Trang Seafoods, the Department calculated NV based on the FOPs reported by the Minh Phu Group and Nha Trang Seafoods for the POR. The Department used data from the Bangladesh import statistics and other publicly available Bangladeshi sources in order to calculate SVs for the Minh Phu Group and Nha Trang Seafoods' FOPs (direct materials, energy, and packing materials) and certain

[43] *See* Surrogate Value Memorandum for details regarding the SVs for movement expenses.

[44] *See* Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) at 590.

[45] *See, e.g., Carbazole Violet Pigment 23 from India: Final Results of the Expedited Five-year (Sunset) Review of the Countervailing Duty Order,* 75 FR 13257 (March 19, 2010) and accompanying Issues and Decision Memorandum at 4–5; *Certain Cut-to-Length Carbon-Quality Steel Plate from Indonesia: Final Results of Expedited Sunset Review,* 70 FR 45692 (August 8, 2005) and accompanying Issues and Decision Memorandum at 4; *See Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review,* 74 FR 2512 (January 15, 2009) and accompanying Issues and Decision Memorandum at 17, 19–20; *See Final Affirmative Countervailing Duty Determination: Certain Hot-Rolled Carbon Steel Flat Products From Thailand,* 66 FR 50410 (October 3, 2001) and accompanying Issues and Decision Memorandum at 23.

[46] *See, e.g., Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 73 FR 24552, 24559 (May 5, 2008) (unchanged in final determination).

[47] *See* Factor Valuations section, below.

movement expenses. To calculate NV, the Department multiplied the reported per-unit factor quantities by publicly available Bangladeshi SVs (except as noted below). Because the statute is silent concerning what constitutes the ''best available information'' for a particular SV, the courts have recognized that on this topic the Department enjoys ''broad discretion to determine the best available information for an antidumping review.'' [48] The Department's practice when selecting the best available information for valuing FOPs is to select, to the extent practicable, SVs which are product-specific, representative of a broad market average, publicly available, contemporaneous with the POR, and exclusive of taxes and duties.[49]

Domestic Producers provided shrimp data for the Philippines published by the PFDA, which, although publicly available, does not encompass the full range of count sizes sold by respondents. Conversely, the shrimp values within the NACA study, which were submitted by certain Vietnamese respondents, are compiled from actual pricing records kept by Bangladeshi farmers, traders, depots, agents, and processors, are count-specific, and publicly available. Therefore, to value the main input, head-on, shell-on shrimp, the Department used data contained in the NACA study.[50]

The Department used United Nations ComTrade Statistics, provided by the UN Department of Economic and Social Affairs' Statistics Division, as its primary source of Bangladeshi SV data.[51] The data represents cumulative values for the calendar year 2007, for inputs classified by the Harmonized Commodity Description and Coding System number. For each input value, we used the average value per unit for that input imported into Bangladesh from all countries that the Department has not previously determined to be NME countries. Import statistics from countries that the Department has determined to be countries which subsidized exports (*i.e.,* Indonesia, South Korea, Thailand, and India) and imports from unspecified countries also were excluded in the calculation of the average value.[52] Lastly, the Department has also excluded imports from Bangladesh into Bangladesh because there is no evidence on the record regarding what these data represent (*e.g.,* re-importations, another category of unspecified imports, or the result of an error in reporting). Thus, these data do not represent the best available information upon which to rely for valuation purposes.[53]

In this case, the Department adjusted the SVs as necessary to ensure a fair calculation of the production costs.[54] First, the Department made adjustments to the SVs for exchange rates and taxes, and converted all applicable items to measurement on a per kg basis. Second, the Department adjusted input prices by including freight costs to render them delivered prices. Specifically, to accord with the decision of the Federal Circuit in *Sigma Corp.* v. *United States,* 117 F.3d 1401, 1408 (Fed. Cir. 1997), the Department added to the Bangladeshi import SVs a surrogate freight cost using the shorter of the reported distance between (1) the domestic supplier and the factory or (2) the nearest seaport and the factory. Where we did not use Bangladeshi Import Statistics, we calculated freight based on the reported distance from the supplier to the factory. For a detailed description of all SVs used for the Minh Phu Group and Nha Trang Seafoods, *see* Surrogate Value Memorandum.

It is the Department's practice to calculate price index adjustors to inflate or deflate, as appropriate, SVs that are not contemporaneous with the POR using the wholesale price index (''WPI'') for the subject country.[55] However, in this case, a WPI was not available for Bangladesh. Therefore, where publicly available information contemporaneous with the POR with which to value factors could not be obtained, SVs were adjusted using the Consumer Price Index (''CPI'') rate for Bangladesh, or the WPI for India or Indonesia (for certain SVs where Bangladeshi data could not be obtained), as published in the International Financial Statistics of the International Monetary Fund. We made currency conversions, where necessary, pursuant to 19 CFR 351.415, to U.S. dollars using the daily exchange rate corresponding to the reported date of each sale. We relied on the daily exchange rates posted on the Import Administration Web site (*http://www.trade.gov/ia/*).[56]

The Department used UN ComTrade to value the raw material and packing material inputs that the Minh Phu Group and Nha Trang Seafoods used to produce the merchandise under review during the POR, except where listed below. For a detailed description of all SVs for respondents, *see* Surrogate Value Memorandum.

We valued electricity using data from the Bangladesh Ministry of Power, Energy, & Mineral Resources. This information was published on their Power Division's Web site.[57]

We valued water using 2007 data from the Asian Development Bank. We inflated the value using the POR average CPI rate.[58]

We valued diesel using data published by the World Bank in ''Bangladesh: Transport at a Glance,'' published in June 2006. We inflated the value using the POR average CPI rate.[59]

To value truck freight and river freight, we used data published in *2008 Statistical Yearbook of Bangladesh* published by the Bangladesh Bureau of Statistics. We inflated the value using the POR average CPI rate.[60]

To value marine insurance, the Department used rates from RJG Consultants. These rates are for sea freight from the Far East Region.[61]

We valued warehouse/cold storage rates published in an article on tropical-seeds.com in July 1997. We inflated the value using the POR average CPI rate.[62]

We valued containerization using information previously available on the Import Administration Web site. We inflated the value using the POR average WPI rate.[63]

The Department valued terminal lift charges using data from the Web sites *http://www.oocl.com/bangladesh/eng/localinformation/localsurcharges/?site=bangladesh&lang=eng* and *http://www.srinternational.com/standard_*

[48] *See Ad Hoc Shrimp Trade Action Comm.* v. *United States,* 618 F.3d 1316, 1322 (Fed. Cir. 2010).

[49] *See, e.g., Electrolytic Manganese Dioxide From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 73 FR 48195 (August 18, 2008) and accompanying Issues and Decision Memorandum at Comment 2.

[50] For a detailed explanation of the Department's valuation of shrimp, *see* Surrogate Value Memorandum at 3.

[51] This can be accessed online at: *http://www.unstats.un.org/unsd/comtrade/.*

[52] *See Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Color Television Receivers From the People's Republic of China,* 69 FR 20594 (April 16, 2004).

[53] *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 75 FR 47771 (August 9, 2010) and accompanying Issues and Decision Memorandum at Comment 6.

[54] *See Grobest & I–Mei Industrial (Vietnam) Co., Ltd., et al.* v. *United States,* Slip Op. 2012–9 (January 18, 2012) at 20.

[55] *See Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Hand Trucks and Certain Parts Thereof From the People's Republic of China,* 69 FR 29509 (May 24, 2004).

[56] *See* Surrogate Value Memorandum.

[57] *See* Surrogate Value Memorandum at 3.

[58] *Id.* at 4.

[59] *Id.* at 5.

[60] *Id.* at 6.

[61] *Id.* at 4.

[62] *Id.* at 3.

[63] *Id.* at 4.

containers.htm. We inflated the value using the POR average WPI rate.[64]

We valued the by-product using shell scrap values from the Memorandum to Barbara E. Tillman, Director, Office of AD/CVD Enforcement VII, through Maureen Flannery, Program Manager, Office of AD/CVD Enforcement VII, from Christian Hughes and Adina Teodorescu, Case Analysts, subject: Surrogate Valuation of Shell Scrap: Freshwater Crawfish Tail Meat from the People's Republic of China (PRC), Administrative Review 9/1/00–8/31/01 and New Shipper Reviews 9/1/00–8/31/01 and 9/1/00–10/15/01. We inflated the value using the POR average WPI rate.[65]

To value factory overhead, selling, general, & administrative expenses, and profit, we used the simple average of the 2009–2010 financial statement of Apex Foods Limited and the 2009–2010 financial statement of Gemini Seafood Limited, both of which are Bangladeshi producers of identical merchandise.[66]

As previously stated, the Department values FOPs in NME cases using the best available information for such factors in a ME country or countries considered appropriate by the administering authority. In so doing, the Department utilizes, to the extent possible, the prices or costs of factors of production in one or more ME countries that are (1) at a comparable level of economic development and (2) significant producers of comparable merchandise.[67]

Previously, to value the respondent's cost of labor, the Department used regression-based wages that captured the worldwide relationship between per capita Gross National Income (''GNI'') and hourly manufacturing wages, pursuant to 19 CFR 351.408(c)(3). However, on May 14, 2010, the Federal Circuit in *Dorbest Ltd.* v. *United States,* 604 F.3d 1363, 1372–73 (Fed. Cir. 2010) (''*Dorbest*''), invalidated 19 CFR 351.408(c)(3). As a consequence of the Federal Circuit's ruling in *Dorbest,* the Department no longer relies on the regression-based wage rate methodology described in its regulations.

In this review, the Department has selected Bangladesh as the surrogate country for the final results. The record contains a labor wage rate for shrimp processing in Bangladesh, published by the Bangladesh Bureau of Statistics. When selecting possible surrogate values for use in an NME proceeding, the Department's preference is to use surrogate values that are publicly available, broad market averages, contemporaneous with the POR, specific to the input in question, and exclusive of taxes.[68] Pursuant to section 773(c)(1) of the Act, it is also the Department's practice to use the best available information to derive surrogate values. The Department considers several factors, including quality, specificity and contemporaneity, to determine the best available information in accordance with the Act. The Department finds this labor wage rate to be the best available information on the record. This data is publicly available, represents a broad market average, specific to the shrimp processing industry, contemporaneous to the POR, and collected from an official Bangladeshi government source in the surrogate country that the Department has selected. Therefore, we note that the BBS data is consistent with the Department's statement of policy regarding the calculation of surrogate value for labor. For further information on the calculation of the labor rate, *see* Surrogate Value Memorandum at 4.

To value brokerage and handling, the Department used a price list of export procedures necessary to export a standardized cargo of goods in India. The price list is publicly available and compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India as published in *Doing Business 2011: India* (published by the World Bank).[69]

Currency Conversion

The Department made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter	Simple average margin (percent)
Minh Phu Group:	
Minh Phat Seafood Co., Ltd., aka	
Minh Phat Seafood aka	
Minh Phu Seafood Export Import Corporation (and affiliates Minh Qui Seafood Co., Ltd. and Minh Phat Seafood Co., Ltd.) aka	
Minh Phu Seafood Corp. aka	
Minh Phu Seafood Corporation aka	
Minh Qui Seafood aka	
Minh Qui Seafood Co., Ltd.	
Minh Phu Seafood Pte aka	
Minh Phat aka	
Minh Qui	
Minh Phu Hau Giang Seafood Co., Ltd	* 0.09
Nha Trang Seafoods Group:	
Nha Trang Seaproduct Company (''Nha Trang Seafoods'') aka	
Nha Trang Seafoods aka	
Nha Trang Seaproduct Company Nha Trang Seafoods aka	
NT Seafoods Corporation (''NT Seafoods'')	
Nha Trang Seafoods—F.89 Joint Stock Company (''Nha Trang Seafoods—F.89'') aka	
NTSF Seafoods Joint Stock Company (''NTSF Seafoods'')	0.00
Amanda Foods (Vietnam) Limited (''Amanda Foods'')	1.03

[64] *Id.* at 5.

[65] *Id.* at 7.

[66] *See* Surrogate Value Memorandum, at Exhibit 2.

[67] *See* section 773(c)(4) of the Act.

[68] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of the Second Administrative Review,* 72 FR 13242 (March 21, 2007) and accompanying Issues and Decision Memorandum at Comment 8B.

[69] *See* Surrogate Value Memorandum at XX.

Exporter	Simple average margin (percent)
Bac Lieu Fisheries Company Limited, aka Bac Lieu Fisheries Company Limited (“Bac Lieu”) aka Bac Lieu Fisheries Joint Stock Company aka Bac Lieu Fisheries Limited Company aka Bac Lieu Fisheries Company Limited aka Bac Lieu Fis	1.03
Camau Frozen Seafood Processing Import Export Corporation (“CAMIMEX”) aka Camimex aka Camau Seafood Factory No. 4 aka Camau Seafood Factory No. 5 aka Camau Frozen Seafood Processing Import & Export aka Camau Frozen Seafood Processing Import Export Corp. (CAMIMEX–FAC 25) aka Frozen Factory No. 4 Camau Frozen Seafood Processing Import Export Corporation (“CAMIMEX”) aka Camimex aka Camau Seafood Factory No. 4 aka Camau Seafood Factory No. 5	0.80
C.P. Vietnam Livestock Company Limited aka C.P. Vietnam Livestock Corporation (“C.P. Vietnam”) aka C.P. Vietnam Livestock Corporation	1.03
Cadovimex Seafood Import-Export and Processing Joint Stock Company (“CADOVIMEX–VIETNAM”) aka Cadovimex-Vietnam aka Cai Doi Vam Seafood Import-Export Company (“Cadovimex”) aka Cai Doi Vam Seafood Import-Export Company (Cadovimex) aka Cai Doi Vam Seafood aka Cai Doi Vam Seafood Im-Ex Company (Cadovimex) aka Cai Doi Vam Seafood Processing Factory aka Caidoivam Seafood Company (Cadovimex) aka Caidoivam Seafood Im-Ex Co	1.03
Cafatex Fishery Joint Stock Corporation (“Cafatex Corp.”) aka Cafatex Fishery Joint Stock Corporation (“CAFATEX CORP.”) aka Cantho Animal Fisheries Product Processing Export Enterprise (Cafatex), aka Cafatex, aka Cafatex Vietnam, aka Xi Nghiep Che Bien Thuy Suc San Xuat Kau Cantho, aka Cas, aka Cas Branch, aka Cafatex Saigon, aka Cafatex Fishery Joint Stock Corporation, aka Cafatex Corporation, aka Taydo Seafood Enterprise aka Cafatex Corp. aka Cafatex Corporation	1.03
Cam Ranh Seafoods Processing Enterprise Company (“Camranh Seafoods”) aka Camranh Seafoods	1.03
Can Tho Agricultural and Animal Products Import Export Company (“CATACO”) aka Can Tho Agricultural Products aka CATACO aka Can Tho Agricultural and Animal Products Imex Company	1.03
Can Tho Import Export Fishery Limited Company (“CAFISH”)	1.03
Coastal Fishery Development aka Coastal Fisheries Development Corporation (“Cofidec”) aka Coastal Fisheries Development Corporation (Cofidec) aka COFIDEC aka Coastal Fisheries Development Corporation aka Coastal Fisheries Development Co. aka Coastal Fisheries Development Corp	1.03
Cuulong Seaproducts Company (“Cuu Long Seapro”) aka Cuu Long Seaproducts Limited (“Cuulong Seapro”) aka Cuulong Seapro aka Cuulong Seaproducts Company (“Cuulong Seapro”) aka Cuu Long Seaproducts Company (“Cuu Long Seapro”) aka Cuu Long Seaproducts Company aka Cuu Long Seapro aka Cuulong Seaproducts Company (“Cuu Long Seapro”) aka Cuu Long Seaproducts Limited (Cuulong Seapro) aka Cuulong Seapro aka Cuulong Seaproduct Company	1.03
Danang Seaproducts Import Export Corporation (“Seaprodex Danang”) aka Danang Seaproducts Import Export Corporation aka Danang Seaproduct Import-Export Corporation aka Danang Seaproducts Import Export aka	

Exporter	Simple average margin (percent)
Tho Quang Seafood Processing & Export Company aka	
Seaprodex Danang aka	
Tho Quang Seafood Processing and Export Company aka	
Tho Quang aka	
Tho Quang Co	1.03
Gallant Ocean (Vietnam) Co., Ltd	1.03
Viet I-Mei Frozen Foods Co., Ltd	1.03
Investment Commerce Fisheries Corporation (''Incomfish'') aka	
Incomfish aka	
Investment Commerce Fisheries Corp., aka	
Incomfish Corp., aka	
Incomfish Corporation aka	
Investment Commerce Fisheries aka	
Investment Commerce Fisheries Corporation aka	
Incomfish Corporation	1.03
Kim Anh Company Limited (''Kim Anh'')	1.03
Minh Hai Export Frozen Seafood Processing Joint Stock Company aka	
Minh Hai Jostoco aka	
Minh Hai Export Frozen Seafood Processing Joint-Stock Company (''Minh Hai Jostoco'') aka	
Minh Hai Export Frozen Seafood Processing Joint Stock Company (''Minh Hai Jostoco'') aka	
Minh Hai Export Frozen Seafood Processing Joint-Stock Company aka	
Minh Hai Joint Stock Seafood Processing Joint-Stock Company aka	
Minh Hai Export Frozen Seafood Processing Joint-Stock Co., aka	
Minh-Hai Export Frozen Seafood Processing Joint-Stock Company	1.03
Minh Hai Joint-Stock Seafoods Processing Company (''Seaprodex Minh Hai'') aka	
Sea Minh Hai aka	
Minh Hai Joint-Stock Seafoods Processing Company aka	
Seaprodex Minh Hai aka	
Seaprodex Min Hai aka	
Seaprodex Minh Hai (Minh Hai Joint Stock Seafoods Processing Co.) aka	
Seaprodex Minh Hai Factory aka	
Seaprodex Minh Hai Factory No. 69 aka	
Seaprodex Minh Hai Workshop 1 aka	
Seaprodex Minh Hai-Factory No. 78 aka	
Workshop I Seaprodex Minh Hai	1.03
Minh Hai Sea Products Import Export Company (''Seaprimex Co'') aka	
Ca Mau Seafood Joint Stock Company (''SEAPRIMEXCO'') aka	
Seaprimexco Vietnam aka	
Seaprimexco aka	
Ca Mau Seafood Joint Stock Company (''Seaprimexco'') aka	
Minh Hai Seaproducts Import Export Corporation aka	
Seaprimexco aka	
Minh Hai Seaproducts Co Ltd. (Seaprimexco) aka	
Ca Mau Seafood Joint Stock Company (''Seaprimexco Vietnam'')	1.03
Ngoc Sinh Private Enterprise aka	
Ngoc Sinh Seafoods aka	
Ngoc Sinh Seafoods Processing and Trading Enterprise aka	
Ngoc Sinh Fisheries aka	
Ngoc Sinh Private Enterprises aka	
Ngoc Sinh Seafoods Processing and Trading Enterprises aka	
Ngoc Sinh aka	
Ngoc Sinh Seafood Processing Company aka	
Ngoc Sinh Seafoods (Private Enterprise)	1.03
Ngoc Tri Seafood Joint Stock Company	1.03
Nhat Duc Co., Ltd.	
Nhat Duc Co., Ltd. (''Nhat Duc'')	1.03
Nha Trang Fisheries Joint Stock Company (''Nha Trang Fisco'') aka	
Nha Trang Fisheries Joint Stock Company aka	
Nhatrang Fisheries Joint Stock Company aka	
Nha Trang Fisco aka	
Nhatrang Fisco aka	
Nha Trang Fisheries Joint Stock Company (''Nha Trang Fisco'') aka	
Nha Trang Fisheries, Joint Stock aka	
Nha Trang Fisheries Joint Stock Company (Nha Trang Fisco)	1.03
Phu Cuong Seafood Processing and Import-Export Co., Ltd. aka.	
Phu Cuong Seafood Processing and Import Export Company Limited aka	
Phu Cuong Jostoco Corp	1.03
Phuong Nam Co., Ltd. (''Phuong Nam'') aka	
Western Seafood Processing and Exporting Factory (''Western Seafood'') aka	
Phuong Nam Foodstuff Corp. aka	
Phuong Nam Co. Ltd	1.03

Exporter	Simple average margin (percent)
Sao Ta Foods Joint Stock Company (''Fimex VN'') aka Sao Ta Foods Joint Stock Company aka Fimex VN aka Sao Ta Seafood Factory aka Saota Seafood Factory	1.03
Soc Trang Aquatic Products and General Import Export Company (''Stapimex'') aka Soc Trang Seafood Joint Stock Company (''Stapimex'') aka Soc Trang Seafood Joint Stock Company aka Soc Trang Aquatic Products and General Import Export Company aka Stapimex aka Soc Trang Aquatic Products and General Import Export Company-(Stapimex) aka Stapimex Soc Trans Aquatic Products and General Import Export Company aka Stapmex	1.03
Thuan Phuoc Seafoods and Trading Corporation aka Frozen Seafoods Factory No. 32 aka Seafoods and Foodstuff Factory aka My Son Seafoods Factory aka Seafoods and Foodstuff Factory Vietnam	1.03
UTXI Aquatic Products Processing Company aka UT XI Aquatic Products Processing Company aka UT–XI Aquatic Products Processing Company aka UTXI aka UTXI Co. Ltd., aka Khanh Loi Seafood Factory aka Hoang Phuong Seafood Factory aka UTXI Aquatic Products Processing Corporation (''UTXICO'') aka UTXI Aquatic Products Processing Corporation aka UTXICO	1.03
Viet Foods Co., Ltd. aka Nam Hai Foodstuff and Export Company Ltd	1.03
Viet Hai Seafood Co., Ltd. aka Vietnam Fish One Co., Ltd. (''Fish One'') aka Viet Hai Seafoods Company Ltd. (''Vietnam Fish One Co. Ltd.'')	1.03
Vietnam Clean Seafood Corporation aka VINA Cleanfood	1.03
Vietnam-wide Entity	25.76

* de minimis.

Public Comment

The Department will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.[70] Interested parties may submit written comments (case briefs) within 30 days of publication of the preliminary results and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.[71] Rebuttal briefs must be limited to issues raised in the case briefs.[72] Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties, who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, filed electronically using Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern Standard Time within 30 days after the date of publication of this notice.[73] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.[74] Parties should confirm by telephone the date, time, and location of the hearing.

Unless the deadline is extended pursuant to section 751(a)(2)(B)(iv) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after issuance of these preliminary results.

Deadline for Submission of Publicly Available Surrogate Value Information

The deadline for submission of publicly available information to value FOPs under 19 CFR 351.408(c) is 20 days after the date of publication of these preliminary results.[75] If an interested party submits factual information less than ten days before, on, or after (if the Department has extended the deadline), the applicable deadline for submission of such factual information, an interested party may submit factual information to rebut, clarify, or correct the factual information no later than ten days after such factual information is served on

[70] *See* 19 CFR 351.224(b).

[71] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[72] *See* 19 CFR 351.309(d)(2).

[73] *See* 19 CFR 351.310(c).

[74] *See* 19 CFR 351.310.

[75] *See* 19 CFR 351.301(c)(3).

the interested party.[76] However, the Department notes that 19 CFR 351.301(c)(1), permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record.[77] Furthermore, the Department generally will not accept business proprietary information in either the surrogate value submissions or the rebuttals thereto, as the regulation regarding the submission of surrogate values allows only for the submission of publicly available information. Additionally, for each piece of factual information submitted with surrogate value rebuttal comments, the interested party must provide a written explanation of what information that is already on the record of the ongoing proceeding that the factual information is rebutting, clarifying, or correcting.

Assessment Rates

Upon issuing the final results of the review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. We will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales.[78] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis.* However, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Cash Deposit Requirements

The following cash deposit requirements, when imposed, will apply to all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Nha Trang Seaproduct Group and Minh Phu will be the rate established in the final results of this administrative review; (2) for any previously reviewed or investigated Vietnam or non-Vietnam exporter, not covered in this administrative review, with a separate rate, the cash deposit rate will be the company-specific rate established in the most recent segment of this proceeding; (3) for all other Vietnam exporters, the cash deposit rate will continue to be the Vietnam-wide rate (*i.e.,* 25.76 percent); and (4) the cash-deposit rate for any non-Vietnam exporter of subject merchandise from Vietnam will be the rate applicable to the Vietnam exporter that supplied that exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213.

Dated: February 28, 2012.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. 2012–5571 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–869]

Large Residential Washers From the Republic of Korea: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Justin Neuman, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0486.

SUPPLEMENTARY INFORMATION:

Background

On January 19, 2012, the Department of Commerce (the Department) initiated the countervailing duty investigation of large residential washers from the Republic of Korea. *See Large Residential Washers From the Republic of Korea: Initiation of Countervailing Duty Investigation,* 77 FR 4279 (January 27, 2012). The current deadline for the completion of the preliminary determination is March 26, 2012.[1]

Postponement of Due Date for the Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which the Department initiated the investigation. However, the Department may postpone making the preliminary determination until no later than 130 days after the date on which the administering authority initiated the investigation if, among other reasons, the petitioner makes a timely request for an extension pursuant to section 703(c)(1)(A) of the Act. In the instant investigation, the petitioner, Whirlpool Corporation, made a timely request on February 28, 2012, requesting a postponement of the preliminary countervailing duty determination to 130 days from the initiation date. *See* 19 CFR 351.205(e) and the petitioner's February 28, 2012, letter requesting postponement of the preliminary determination.

Therefore, pursuant to 703(c)(1)(A) of the Act and because the Department does not find any compelling reason to deny the request, we are extending the due date for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, or May 28, 2012. Because May 28, 2012, falls on a federal holiday, the deadline for the completion of the preliminary determination is now May 29, 2012, the first business day after the 130th day from initiation. *See Next Business Day Rule.*

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(l).

[76] *See* 19 CFR 351.301(c)(1).

[77] *See, e.g., Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007), and accompanying Issues and Decision Memorandum at Comment 2.

[78] *See* 19 CFR 351.212(b)(1).

[1] The statutory deadline for the preliminary determination is March 24, 2012, which is a Saturday. When the statutory deadline falls on a weekend, it is the Department's practice to issue the determination on the next business day, which in this case would be March 26, 2012. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005) (*Next Business Day Rule*).

Dated: March 1, 2012.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. 2012–5567 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

U.S. Education Mission to Brazil; Brasilia, Rio de Janeiro and São Paulo, Brazil, August 30–September 6, 2012

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

Mission Description

The United States Department of Commerce, International Trade Administration, U.S. and Foreign Commercial Service (US&FCS), is organizing an education mission to Brazil (Brasilia, Rio de Janeiro, São Paulo) and is partnering with the United States Department of State's EducationUSA Advising Centers. The emphasis will be on U.S. higher education, focusing on, in order of importance, intensive English language programs, undergraduate and graduate programs, and community college programs. English language programs and other continuing education programs seeking to participate should be part of a U.S. college or university and accredited through them. Community colleges, undergraduate and graduate programs seeking to participate should be accredited by a recognized accreditation body listed in Council for Higher Education Accreditation (CHEA), in the Association of Specialized and Professional Accreditors (ASPA), or any accrediting body recognized by the U.S. Department of Education.

This mission will seek to connect United States education institutions to potential students and university/institution partners in Brazil. The mission will include student fairs organized by EducationUSA, embassy briefings, site visits, and networking events. Brasilia, Rio de Janeiro and São Paulo are three of the top cities for recruiting Brazilian students to the United States. Participating in the Education Mission, rather than traveling to these markets independently, will enhance the schools' ability to secure the appropriate meetings, especially in light of the high level engagement and support of U.S. education by the U.S. Ambassador in Brazil.

Commercial Setting

There are several types of opportunities for U.S. universities and institutions of higher learning in Brazil: (1) Attracting Brazilian students to the United States (2) establishing a campus in Brazil to offer courses and programs and (3) online training programs.

In March 2010, the United States and Brazil issued a joint statement to reaffirm the U.S.-Brazil Partnership for Education. Under the Partnership, the two countries endeavor to share information and expand cooperation in areas including promoting educational excellence; promoting diversity and equal opportunity in education; assessment, indicators and accountability; professional development for teachers and administrators; vocational-technical education; second language learning (English/Portuguese); U.S. community colleges and Brazilian federal institutes; and higher education cooperation and mobility. The partnership is working to strengthen educational exchanges between research and higher education institutions in the Science, Technology, Environment and Math fields.[1] Science Without Borders, a Brazilian government program, provides scholarships to Brazilian undergraduate students for one year of study at colleges and universities in the U.S. Scholarships are given primarily in the fields of science, technology, engineering and mathematics. Students then return to Brazil to complete their degrees.

The United States has long been a top destination for Brazilian students looking to study abroad. Since 2006, the United States has seen an increase in the number of Brazilian students. There are some 8,777 Brazilians currently studying in the United States, a 16% increase from 2006; placing Brazil in 13th place among country of origin of international students in the U.S. The majority (46.3%) of Brazilian students in the United States are undergraduate students with Brazilian graduate students not too far behind at 34.8%.[2] The new agreement between the United States and Brazil could help reverse a contraction in the number of Brazilians studying overseas that followed a fiscal squeeze in the 1990s [3] when the government restricted fellowships for university study abroad, which made it possible for about 20,000 Brazilians to obtain their advanced degrees in the United States and Europe.[4] Brazilian students and employers in Brazil have expressed the importance of education in areas that are well-aligned with the Brazilian job market. According to a recent Institute for Applied Economic Research (IPEA) study, 5.5 million workers in Brazil were unable to find jobs because they lacked the training and skills needed for current job openings. Brazil hopes to expand educational opportunities for students in order to meet employer's needs in commerce, high technology, engineering, and construction sectors.[5]

The first stop on the mission itinerary is Brasilia, the capital city of Brazil. This visit would give the delegates an opportunity to directly interact with officials from the Government of Brazil regarding education policies. Brasilia has more than 114 universities recognized by the Ministry of Education (MEC). Brasilia would offer the delegates meetings with appropriate Brazilian government officials, an embassy reception, access to local bilingual high schools, and a student fair.

Then the group will travel to São Paulo. The highest rate of enrollment in schools is found in São Paulo, which is the economically wealthiest region of the nation. The mission participants will have the opportunity to participate in student recruitment fairs, high school/university visits and optional one-on-one meetings. The universities in São Paulo are leaders in terms of education and research in Brazil.[6] The city of São Paulo has several colleges and universities while the state of São Paulo has more than 578 universities.

Finally, the delegation will travel to Rio de Janeiro to participate in a student recruitment fair and site visits to American and other bilingual high schools. The city of Rio de Janeiro boasts 99 higher education institutions which include 53 University-preparatory schools, 6 major universities and 47 private schools of higher education. The state of Rio de

[1] Bureau of Western Hemisphere Affairs, *The United States and Brazil: An Education Partnership for the 21st Century, http://www.state.gov/p/wha/rls/fs/2011/158610.htm,* March 19, 2011.

[2] *Open Doors: Report on International Educational Exchange,* published annually by IIE with support from the U.S. Department of State's Bureau of Educational and Cultural Affairs, *http://www.iie.org/Research-and-Publications/Open-Doors/Data/Fact-Sheets-by-Country/~/media/Files/Corporate/Open-Doors/Fact-Sheets-2011/Country/Brazil%20Fact%20Sheet%20-%20Open%20Doors%202011.ashx.*

[3] Hennigan, Tom, *Brazil: US, Europe Pursue Higher Education Ties,* April 10, 2011, Issue 166.

[4] U.S. Library of Congress, *Colleges and Universities: Brazil, http://countrystudies.us/brazil/53.htm.*

[5] Nogueira, Danielle for Infosurhoy.com, *Brazil: Educational System Threatening Economic Growth,* 03/02/11.

[6] *http://www.mapsofworld.com/cities/brazil/sao-paulo/education.html.*

Janeiro has more than 137 upper-learning institutions. Three of the nation's top ranking universities, Rio de Janeiro State University, Federal University of Rio de Janeiro, and Pontifical Catholic University, are located in the city of Rio de Janeiro.[7]

Mission Goals

The goals of the United States Education Mission to Brazil are: (1) To help participants gain market exposure and to introduce participants to the vibrant Brazilian market in the three main metropolitan cities of Brasilia, São Paulo, and Rio de Janeiro; (2) to help participants assess current and future business prospects by establishing valuable contacts with prospective students and educational institutions/partners; and (3) to help participants develop market knowledge and relationships leading to student recruitment and potential partnerships.

Mission Scenario

Participation in the mission will include the following:

- Pre-travel briefings/webinars;
- Embassy/consulate and industry briefings;
- Reception with Ambassador;
- Student Fairs and local visits organized by EducationUSA in Brasilia, Rio de Janeiro and São Paulo;
- Airport transfers in Brasilia, São Paulo, Rio de Janeiro;
- Site visit in Brasilia and Rio de Janeiro; and
- Optional: Pre-scheduled meetings with educational partners in São Paulo

Proposed Mission Schedule—August 30–September 6, 2012

Brasilia—August 30–September 1, 2012

Thursday–August 30, 2012

—Arrive in Brasilia
—Check into hotel

Friday, August 31, 2012

—Ministry meetings/briefing on scholarship program, Visa Briefing
—Local visits to the American high school
—Lunch or evening reception with Ambassador

Saturday, September 1, 2012

—Student Fairs organized by EducationUSA, Under Secretary to open

São Paulo—September 2–4, 2012

Sunday, September 2, 2012

—Arrive in São Paulo and check into hotel
—Free Time

Monday—September 3, 2012

—11 a.m.–2 p.m. Visit to local high school
—5 p.m. EducationUSA Fair

Tuesday—September 4, 2012

—11 a.m.–1 p.m. Visit to local high school
—Depart for Rio de Janeiro

Rio de Janeiro—September 5–6, 2012

Wednesday—September 5, 2012

—Local high school visits
—Student fair organized by EducationUSA

Thursday—September 6, 2012

—No host breakfast/lunch; debrief with Under Secretary
—Depart for United States, or for the universities continuing on the EducationUSA South America Circuit, depart for Buenos Aires.

The Department of Commerce mission is only in Brazil. For schools interested in exploring additional markets in South America, Education USA offers a series of student fairs in the following cities after the mission:

—Buenos Aires—September 7th—Friday
—Santiago—September 8th—Saturday
—Lima—September 11th—Tuesday
—Quito—September 13th—Thursday
—Guayaquil—September 15th—Saturday
—Bogota—September 17th—Monday
—Caracas—September 19th—Wednesday

Participation Requirements

All parties interested in participating in the mission to Brazil must submit a complete application package for consideration to the U.S. Department of Commerce. They also must complete and submit the online application for consideration by the EducationUSA South America Fair. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. The mission will open on a first-come, first-served basis to a minimum of 50 and a maximum of 60 appropriately accredited U.S. institutions.

Selection Criteria for Participation

- Applicant must be appropriately accredited as per paragraph one.
- Consistency of the applicant's goals and objectives with the stated scope of the mission.
- Timeliness of signed application and participation agreement by institution Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and will not be considered during the selection process.

Conditions for Participation

An applicant must submit a timely, completed and signed mission application and supplemental application materials, including adequate information on courses offerings, primary market objectives, and goals for participation. The institution must be represented at the student fair by an employee. No agents will be allowed to represent a school on the mission or participate at the student fair. Agents will also not be allowed into the fairs to solicit new partnerships. If the Department of Commerce receives an incomplete application, the Department may reject the application, request additional information, or take the lack of information into account when evaluating the applications.

Each applicant must also certify that the services it seeks to export through the mission are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have at least 51 percent U.S. content of the value of the service.

Fees and Expenses

After an institution has been selected to participate on the mission, a payment to the South America EducationUSA fair in the form of a participation fee is required. The participation fee is $3,750 dollars for one principal representative from each regionally accredited educational institution per city until May 31st and $4,110 dollars for applications received after this date. The fee for each additional representative is $300. Expenses for lodging, some meals, incidentals, and all travel (except for transportation to and from airports in-country, previously noted) will be the responsibility of each mission participant. The EducationUSA Fair offers government rates or below-government rates in all hotels in the circuit.

Timeframe for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the Commerce Department trade mission calendar (*http://export.gov/industry/education/*) and other Internet Web sites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier

[7] *http://en.wikipedia.org/wiki/Rio_de_Janeiro#Education.*

groups, and publicity at industry meetings, symposia, conferences, and trade shows. Recruitment for the mission will begin immediately and conclude no later than August 15, 2012. The mission will be open on a first come first served basis. Applications received after that date will be considered only if space and scheduling constraints permit.

Contact Information

U.S. Commercial Service in Brazil

Patricia S. Marega, Business Development Specialist, São Paulo Tel: (55–11) 5186–7482, *patricia.marega@trade.gov.*

U.S. Export Assistance Center

Joan Kanlian, Westchester USEAC Director, Tel: 914–682–6712, Email: *Joan.Kanlian@trade.gov.*

Elnora Moye,

Trade Program Assistant.

[FR Doc. 2012–5451 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket Number: 120301149–2149–01]

Request for Comments on the 5-Year Review of NOAA's Policy on Partnerships in the Provision of Environmental Information

AGENCY: National Weather Service (NWS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for comments.

SUMMARY: The National Weather Service of the National Oceanic and Atmospheric Administration publishes this notice to request comments on NOAA's Policy on Partnerships in the Provision of Environmental Information. This request for comments is being made as part of a period periodic review of the Policy's effectiveness.

DATES: Comments must be received by 5 p.m. (EDT), April 30, 2012.

ADDRESSES: Electronic comments are preferred. A webform for comments is available at: *http://www.nws.noaa.gov/survey/policy_partnerships_comments.php.*

Written comments may be mailed in hard copy to the following address: Partnership Policy Comments, U.S. Department of Commerce, NOAA 1325 East-West Highway, Room 17205, Silver Spring, MD 20910.

A copy of NOAA's Policy on Partnerships in the Provision of Environmental Information as well as a complete history can be found on the NOAA Web site at: *http://www.noaa.gov/partnershippolicy/.*

FOR FURTHER INFORMATION CONTACT: Jennifer Sprague, 301–713–0217.

SUPPLEMENTARY INFORMATION: The National Weather Service of the National Oceanic and Atmospheric Administration (NOAA) is undertaking a review of NOAA's Policy on Partnerships in the Provision of Environmental Information. This Policy applies to the weather, water, climate and related environmental information services of the National Oceanic and Atmospheric Administration. It sets forth basic principles to be applied in making decisions regarding these information services. The Policy is intended to strengthen the existing partnership between government, academia and the private sector, which is a partnership that provides the nation with high quality weather, water, climate and related environmental information.

The Policy calls for a periodic review of its effectiveness, and NOAA is seeking public comments to aid in this review.

Dated: March 2, 2012.

David Murray,

Director, Management and Organizational Division, Office of the Chief Financial Officer, National Weather Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2012–5544 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XO45

Marine Mammals; File No. 14241

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that a major amendment to Permit No. 14241–02 has been issued to Dr. Peter Tyack, Woods Hole Oceanographic Institution, Woods Hole, MA for research on marine mammals.

ADDRESSES: The permit amendment and related documents are available for review upon written request or by appointment in the following offices: See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Tammy Adams or Carrie Hubard, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On December 16, 2011, notice was published in the **Federal Register** (76 FR 78242) that a request for an amendment to Permit No. 14241–02 to conduct research on marine mammals had been submitted by the above-named applicant. The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The permit has been amended to include (1) adding waters off Florida to the project for tagging to study risks of entanglement in mid-Atlantic states; (2) one new species, Atlantic spotted dolphin (*Stenella frontalis*), for field work in waters off Florida, Georgia, North Carolina, South Carolina, and Virginia; (3) a new project to Dtag the following species in waters off the west coast of North America: Baird's beaked whale (*Berardius bairdii*), Cuvier's beaked whale (*Ziphius cavirostris*), Risso's dolphin (*Grampus griseus*), killer whale (*Orcinus orca*) and Mesoplodont beaked whales (*Mesoplodon* spp); (4) a new procedure for marking cetaceans with zinc oxide; (5) satellite tagging to long-finned pilot whales in approaches to the Mediterranean; and (6) switching some of the playback takes initially located in the Mediterranean and eastern North Atlantic to the same stocks of long-finned (*Globicephala melas*) and short-finned (*G. macrorhynchus*) pilot whales off Cape Hatteras. The amendment is valid through the original expiration date of the permit, July 31, 2014.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Documents may be reviewed in the following locations:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376;

Northwest Region, NMFS, 7600 Sand Point Way NE., BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206) 526–6150; fax (206) 526–6426;

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach,

CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018;

Northeast Region, NMFS, 55 Great Republic Drive, Gloucester, MA 01930; phone (978) 281–9328; fax (978) 281–9394; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

Dated: March 2, 2012.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–5556 Filed 3–6–12; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 15 March 2012, at 10 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW., Washington DC, 20001–2728. Items of discussion may include buildings, parks, and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *www.cfa.gov*. Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *staff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated: February 29, 2012 in Washington DC.

Thomas Luebke,

AIA, Secretary.

[FR Doc. 2012–5357 Filed 3–6–12; 8:45 am]

BILLING CODE 6331–01–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Information Collection To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; Initial Certification

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Notice; request for comments.

SUMMARY: The Committee for Purchase from People Who Are Blind or Severely Disabled (The Committee) will submit the collections of information listed below to OMB for approval under the provisions of the Paperwork Reduction Act. This notice solicits comments on these collections of information.

DATES: Submit your written comments on the information collection on or before May 7, 2012.

ADDRESSES: Mail your comments on the requirement to Lou Bartalot, Director Compliance and Review, Committee for Purchase from People Who Are Blind or Severely Disabled, 1421 Jefferson Davis Highway, Jefferson Plaza 2, Suite 10800, Arlington, VA 22202–3259; fax (703) 603–0655; or email *rulecomments@abilityone.gov.*

FOR FURTHER INFORMATION CONTACT: To request a copy of the applicable forms or explanatory material, contact Edward Yang at information in above paragraph.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). The Committee plans to submit a request to OMB to renew its approval of the collections of information concerning annual certification of nonprofit agencies serving people who are blind or who have other significant disabilities to participate in the AbilityOne Program. The Committee is requesting a 3-year term of approval for these information collection activities.

Federal agencies may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for these collections of information are 3037–0002 and 3037–0001.

The JWOD Act of 1971 (41 U.S.C. Chapter 85) is the authorizing legislation for the AbilityOne Program. The AbilityOne Program creates jobs and training opportunities for people who are blind or who have other severe disabilities. Its primary means of doing so is by requiring Government agencies to purchase selected products and services from nonprofit agencies employing such individuals. The AbilityOne Program is administered by the Committee. Two national, independent organizations, National Industries for the Blind (NIB) and NISH, help State and private nonprofit agencies participate in the AbilityOne Program.

The implementing regulations for the JWOD Act, which are located at 41 CFR Chapter 51, provide the requirements, procedures, and standards for the AbilityOne Program. Section 51–4.3 of the regulations sets forth the standards that a nonprofit agency must meet to maintain qualification for participation in the AbilityOne Program. Under this section of the regulations, a nonprofit agency that wants to continue to participate in the AbilityOne Program must submit a completed copy of the appropriate Annual Certification form (Committee Form 403 or 404). This documentation helps the Committee determine whether the applicant nonprofit agency is meeting the requirements of the AbilityOne Program.

This information collection renewal request seeks approval for the Committee to continue to collect the information required under 41 CFR 51–4.3 of the regulations so that the Committee can continue to verify the appropriateness of nonprofit agencies that would like to participate in the JWOD Program. Both forms have added three new questions concerning the number of veterans employed at the agencies doing direct labor and the wages paid to veterans working on AbilityOne projects and have revised the language at the bottom of the certification section.

Title: Annual Certification—Qualified Nonprofit Agency Serving People Who Are Blind, 41 CFR 51–4.3.

OMB Control Number: 3037–0001.

Form Number: Committee Form 403.

Description of Respondents: Nonprofit agencies serving people who are blind that participate in the JWOD Program.

Annual Number of Respondents: About 70 nonprofit agencies serving people who are blind will annually request to be verified for participation in the AbilityOne Program.

Total Annual Burden Hours: Burden is estimated to average 6 hours per respondent. Total annual burden is 420 hours. Note: this burden estimate is only for the reporting of information; a separate burden estimate exists for the recordkeeping requirement.

Title: Initial Certification—Qualified Nonprofit Agency Serving People Who Are Severely Disabled, 41 CFR 51–4.3.

OMB Control Number: 3037–0002.

Form Number: Committee Form 404.

Description of Respondents: Nonprofit agencies serving people who are severely disabled that participate in the JWOD Program.

Annual Number of Respondents: About 550 nonprofit agencies serving people who are severely disabled will annually request to be verified for participation in the JWOD Program.

Total Annual Burden Hours: Burden is estimated to average 6 hours per respondent. Total annual burden is 3,300 hours. Note: this burden estimate is only for the reporting of information; a separate burden estimate exists for the recordkeeping requirement.

We invite comments concerning this renewal on: (1) Whether the collection of information is necessary for the proper performance of our agency's functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2012–5452 Filed 3–6–12; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 11–53]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 11–53 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: March 1, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

FEB 24 2012

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 11-53, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Kuwait for defense articles and services estimated to cost $105 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

William E. Landay III
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

BILLLING CODE 5001–06–C

Transmittal No. 11–53

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as Amended

(i) *Prospective Purchaser:* Kuwait

(ii) *Total Estimated Value:*

Major Defense Equipment * ...	$81 million
Other	$24 million
TOTAL	$105 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 80 AIM–9X–2 SIDEWINDER Block II All-Up-Round Missiles, 26 CATM–9X–2 Captive Air Training Missiles, 2 CATM–9X–2 Block II Missile Guidance Units, 8 AIM–9X–2 Block II Tactical Guidance Units, 2 Dummy Air Training Missiles, containers, missile support and test equipment, provisioning, spare and repair parts, personnel training and training equipment, publications and technical data, U.S. Government and contractor technical assistance and other related logistics support.

(iv) *Military Department:* Navy (ABI)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Annex attached

* as defined in Section 47(6) of the Arms Export Control Act.

(viii) *Date Report Delivered to Congress:* 24 February 2012

POLICY JUSTIFICATION

Kuwait—AIM–9X–2 SIDEWINDER Missiles

The Government of Kuwait has requested a possible sale of 80 AIM–9X–2 SIDEWINDER Block II All-Up-Round Missiles, 26 CATM–9X–2 Captive Air Training Missiles, 2 CATM–9X–2 Block II Missile Guidance Units, 8 AIM–9X–2 Block II Tactical Guidance Units, 2 Dummy Air Training Missiles, containers, missile support and test equipment, provisioning, spare and repair parts, personnel training and training equipment, publications and technical data, U.S. Government and contractor technical assistance and other related logistics support. The estimated cost is $105 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been, and continues to be, an important force for political stability and economic progress in the Middle East.

The Kuwait Air Force is modernizing its fighter aircraft to better support its own air defense needs. The proposed sale of AIM–9X–2 missiles will enhance Kuwait's interoperability with the U.S. and among other Central Command nations, making it a more valuable partner in an increasingly important area of the world.

The proposed sale of this weapon system will not alter the basic military balance in the region.

The prime contractor will be Raytheon Missile Systems Company in Tucson, Arizona. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will require travel of U.S. Government or contractor representatives to Kuwait on a temporary basis for program technical support and management oversight.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 11–53

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AIM–9X–2 SIDEWINDER Block II Missile represents a substantial increase in missile acquisition and kinematics performance over the AIM–9M and replaces the AIM–9X–1 Block I missile configuration. The missile includes a high off bore-sight seeker, enhanced countermeasure rejection capability, low drag/high angle of attack airframe and the ability to integrate the Helmet Mounted Cueing System. The software algorithms are the most sensitive portion of the AIM–9X–2 missile. The software continues to be modified via a pre-planned product improvement (P^3I) program in order to improve its counter-countermeasures capabilities. No software source code or algorithms will be released.

2. The AIM–9X–2 will result in the transfer of sensitive technology and information. The equipment, hardware, and documentation are classified Confidential. The software and operational performance are classified Secret. The seeker/guidance control section and the target detector are Confidential and contain sensitive state-of-the-art technology. Manuals and technical documentation that are necessary or support operational use and organizational management are classified up to Secret. Performance and operating logic of the counter-countermeasures circuits are classified Secret. The hardware, software, and data identified are classified to protect vulnerabilities, design and performance parameters and similar critical information.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

[FR Doc. 2012–5446 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability for Exclusive, Non-Exclusive, or Partially-Exclusive Licensing of an Invention Concerning a Radiation Detector System for Locating and Identifying Special Nuclear Material in Moving Vehicles

AGENCY: Defense Threat Reduction Agency, Department of Defense.

ACTION: Notice.

SUMMARY: Announcement is made of the availability for licensing of the invention set forth in ''Radiation Detector System for Locating and Identifying Special Nuclear Material in Moving Vehicles,'' U.S. Patent 8,110,807, issued February 7, 2012. This invention is owned by the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of the results of federally-funded research and development.

ADDRESSES: Director, Defense Threat Reduction Agency, Attn: General Counsel, 8725 John J. Kingman Road, Mail Stop 6201, Fort Belvoir VA 22060–6201.

FOR FURTHER INFORMATION CONTACT: Licensing or patent issues, Ellen Klann, Patent Counsel, Office of General Counsel, Defense Threat Reduction Agency, telephone: (703) 767–4561, fax: (703) 767–4550.

SUPPLEMENTARY INFORMATION: The invention uses a series of combined passive neutron and gamma ray sensors and sensor aggregators, systematically placed along a path of commercial traffic, for example an airport runway, combined with a pulsed source of monoenergetic gamma rays and low energy neutrons. The pulsed source produces a short interrogation pulse of monoenergetic gamma rays and low energy neutrons. These gamma rays induce a fission reaction in any fissile material in their path, such as in a moving vehicle, creating gamma rays and neutrons. The passive sensors located in the path of the moving vehicle detect the resultant gamma and neutron products of the reaction.

Dated: March 2, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–5545 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

DoDEA Grants to Military Connected Local Educational Agencies for Academic and Support Programs (MCASP)

AGENCY: Department of Defense Education Activity, Department of Defense.

ACTION: FY 2012 Grant program announcement.

SUMMARY: DoDEA seeks full applications from eligible local educational agencies (LEAs).

DATES:

1. Deadline for Transmittal of Full Applications: April 13, 2012.

2. Applications Package/Instructions Available on www.grants.gov: On or about March 1, 2012.

3. Grants Awarded: On or about June 1, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Fatimah Dozier, Grant Program Manager, DoDEA, email: *fatimah.dozier@hq.dodea.edu,* telephone: 703–588–3129.

SUPPLEMENTARY INFORMATION:

Funding Opportunity Description

The FY 2012 grants to Military-Connected Local Educational Agencies for Academic and Support Programs (MCASP) aim to strengthen family-school-community relationships and enhance student achievement for military dependent students. Applicants may choose to design their projects with academic goals, family engagement goals, or a combination of both. Projects should focus on no more than two program areas. Academically-focused projects should strengthen teacher content knowledge and skills through sustained professional development and, in most cases, encourage integration of technology into the curriculum. Family engagement and support projects should address the social-emotional needs of military families and aim to improve school climate. However, grant funds must be used for programs that directly support the student, and cannot be used for programs that only support family members.

Awards will be made to local educational agencies (LEAs) on behalf of their eligible school(s). LEAs must have at least a five percent military dependent student enrollment at the district level. Eligible schools must have at least a 15 percent military dependent student enrollment. Although funding is related to military dependent student enrollment, it is expected that the proposed programs will serve all students at the target schools.

The following two caveats should be noted:

- The impact on the military dependent student subgroups should be demonstrable.
- Family/support programs must focus primarily on military dependent students.

The application package may be found at *www.militaryk12partners.dodea.edu* and *www.grants.gov.* The full application is due on April 13, 2012.

Definition of *Military Dependent Student:* The term, *military dependent student,* is defined as an elementary or secondary school student who is a dependent of a member of the Armed Forces or a civilian employee of the Department of Defense who is employed on Federal property.

Authorization:

- Section 574(d) of Public Law 109–364, as amended; Title 10 U.S.C. Section 2192(b) and Title 10 U.S.C. Section 2193a.

CFDA Number

- CFDA 12.556: Competitive Grants: Promoting K–12 Student Achievement at Military-Connected Schools.

PK–12 Education

Research-based strategies: DoDEA supports research-based programs that aim to increase student achievement; strengthen family, school, and community engagement; and foster a positive school climate for military dependent children. Research-based strategies:

- Are not limited to a research-based curriculum, but may be teaching and learning strategies that often cut across all content areas and all grade levels.
- Include both valid and innovative programs.

Student achievement: Regarding academic programs, LEAs must employ strategies with demonstrated effectiveness in improving student achievement. Achievement should include but is not limited to measurements of performance on state norm- and/or criterion-referenced assessments. Within this context, projects may include research-based programs that promote college and career readiness or provide extended learning opportunities.

Note: It is understood that some curricular areas and grade levels will not have state norm- or criterion-referenced tests to demonstrate need and reveal improvement. However, the LEA must present multiple data sources to demonstrate need and propose a cost-effective plan to demonstrate increased student academic achievement in those areas.

Support programs: Family engagement and support programs must employ strategies to create a positive school climate and address the social-emotional needs of military dependent students. This includes, but is not limited to, guidance counseling, peer support groups, and parental involvement programs.

Priorities

For the FY12 grant program, there are three priorities, and each applicant must include at least one priority area in their project design. Overall, projects should focus on no more than two program areas. While applicants are permitted to choose more than two program areas, submitting an application that addresses additional areas may result in an unfocused program design. No additional points will be assigned to proposals that incorporate more than one of these priority areas. Proposals may include programs outside of these priorities. Program areas are any K–12 academic content support (English, Math, Science, Social Studies, ESL, or Special Education) and military student socio-emotional support.

Priority #1: Science, technology, engineering, and math (STEM): Projects include strategies to infuse STEM principles throughout the curriculum. For example, a project that focuses only on math would not be given priority points for this area. The intent is to encourage STEM-integration across several content areas.

Priority #2: Strategic foreign languages: Projects include establishment or expansion of foreign language learning, specifically less commonly taught languages such as Asian/Pacific languages and Middle Eastern languages. Programs under this priority may include virtual learning, intensive summer instruction for teachers and students, and immersion courses.

Priority #3: Parent, family, and community engagement: Projects include ongoing, systemic strategies for parent and family engagement. Strategies may include parent training and support, resources and materials, and community involvement activities. Grant funds must be used for programs that directly support the student, and cannot be used for programs that only support family members.

In addition, there are two competitive priorities:

High concentration of military dependent students: An applicant may receive five additional points if one or more of the eligible schools have a military dependent student enrollment of 50 percent or more.

New applicants: Applicants may receive five additional points if the LEA has never previously received a DoDEA grant award.

Eligibility

Applicants are limited to LEAs that have at least a 5 percent military dependent student enrollment at the district level. Eligible schools within the district must have at least a 15 percent military dependent student enrollment. Although funding is related to military dependent student enrollment, it is expected that the proposed programs will serve all students at the target

schools. Funds may be used for programs at any grade level.

Current DoDEA grant recipients are eligible to apply for a FY 2012 MCASP grant if they have eligible schools that are not named (that is, not receiving services) from any of their existing DoDEA grant awards, unless the current grant is scheduled to end on August 31, 2012.

Funding Formula

The funding formula is based on the number of military dependent students at eligible (target) school(s). For example, an LEA with 101–200 students may propose any amount between $135,000 and $270,000. The dollar figures below are for the entire 3-year grant period.

Total military dependent students at target school(s)	Minimum award ($)	Maximum award ($)
100 or fewer	$100,000	$135,000
101–200	135,000	270,000
201–300	270,000	405,000
301–400	405,000	540,000
401–500	540,000	675,000
501–600	675,000	810,000
601–700	810,000	945,000
701–800	945,000	1,080,000
801–900	1,080,000	1,215,000
901–1,000	1,215,000	1,350,000
1,001–1,100	1,350,000	1,485,000
1,101–1,200	1,485,000	1,620,000
1,201–1,300	1,620,000	1,755,000
1,301–1,400	1,755,000	1,890,000
1,401–1,500	1,890,000	2,025,000
1,501–1,600	2,025,000	2,160,000
1,601–1,700	2,160,000	2,295,000
Above 1,700	2,295,000	2,500,000

Award Information

Project Period: June 1, 2012 to August 31, 2015.

Estimated Available Funds: $25,000,000.

Estimated Range of Awards: $100,000 to $2,500,000.

Estimated Average Award Size: $1,000,000.

Estimated Number of Awards: 30.

Minimum Award: $100,000 (100 or fewer military dependent students).

Maximum Award: $2,500,000 (1,700 or more military dependent students).

Expected Dates

• Full Applications Available: On or about February 22, 2012.

• *Live Technical Assistance Webinar #1: March 8, 2012, 3 p.m. ET.

• *Live Technical Assistance Webinar #2: March 9, 2012, 11 a.m. ET.

• Deadline for Intent to Apply (optional): March 14, 2012.

• Deadline for Transmittal of Applications through www.grants.gov: April 13, 2012, 11:59 p.m. ET.

• Grants Awarded: On or about June 1, 2012.

*See application instructions on www.grants.gov for information on how to access the webinars.

Evaluation Criteria

The Project Narrative may not exceed 15 pages in length. The Project Narrative describes, in sufficient detail, how the project will be implemented and includes the Evaluation Criteria in Sections A–F below. The application will be reviewed and scored according to the quality of the responses to the requirements in Sections A–F. The Project Narrative, with all sections included, may be no longer than 15 pages.

Section A: Needs Assessment (10 points)

• Provide relevant school district data or background information, including the connection to the military installation(s).

• State student achievement needs and/or lack of educational opportunities at target schools.

• Cite multiple sources, primarily quantitative data, to confirm the need.

• Explain why current or past efforts failed to resolve the need, if applicable.

• Include other relevant information, e.g., the consequences of *not* addressing the need.

Section B: Project Goals (10 points)

• Include goals that (1) relate to the program's purpose, (2) lead to the desired results, and (3) are achievable through the project's interventions and strategies.

• Express goals broadly, such as: Increase K–5 student achievement in mathematics. Applications should have one goal related to each program area selected, with the recommendation that no more than two program areas are chosen.

• Include outcomes that are (1) measurable and reasonable and (2) related to baseline school, district, and state data as well as the relevant literature.

• Specify outcome timeframes, measurement tools, and target populations. Measurement tools should be an above school-level assessment(s), such as norm- or criterion-referenced standardized state or national test. The baseline should be referenced. The timeframe should be sufficient for strategies to achieve the expected results. Consider the following example of an outcome:

By June 2015, ____ percent of the ____ grade students in the target schools will score proficient or above on the state _____ assessment, an increase of ____ percent over the SY10–11 level.

• Interim outcomes are tied to the goal and are presented as specific measurements that assess each year of the project. Typically, each goal will have multiple interim outcomes.

By the end of SY11–12, _____ percent of the ____ grade students in the target schools will score proficient or above on the state _____ assessment, an increase of ____ percent over the SY10–11 average.

Notes:

—Grantees may have many goals, however it is highly recommended to design a project that includes manageable and reasonable data collection and reporting. DoDEA requires quarterly reporting so the greater the number of goals, the more complex and burdensome the evaluation and reporting becomes.

—With academic programs, the measuring tool is usually a state assessment. For some programs, such as PK–2 Academic and Support, other measuring tools must be selected.

—For goals assessed by changes in attitude or behavior, grantees should use validated surveys or scales. Be aware that baseline measurements for the target population must be taken in order to be able to document changes as a result of project activities.

Section C: Project Plan (30 points)

• Include strategies that have demonstrated effectiveness in improving student achievement in the core curricular areas. The research base should be summarized in this section and details, including references and links should be provided in the appended bibliography.

• Address the issues identified in the needs assessment. If applicable, an explanation of how the project fits into the district or school's improvement plan or the LEA's strategic plan should be included.

• Incorporate strategies for sustained professional development/capacity building related to each program area goal.

Notes:

—The strategies, actions, and a timeline for each goal should be presented. Strategies should work as interrelated parts of a whole.

—Actions are specific steps to accomplish the strategies that occur at specific times and usually involve direct services to students, educators, or other stakeholders. Strategies must be aligned with the goals and outcomes listed above. A well-written strategy section should answer:

1. What strategies are employed?
2. Why were the strategies selected?

3. How will the strategies help achieve the stated outcomes?
4. What evidence shows the strategies to be effective?
5. *If applicable,* how will the strategies work together to achieve the outcomes?

• Describe actions for each strategy. The section outlining actions may be framed with a chart shown in the example below. Charts may use a 10-point font.

Strategies	Actions
EXAMPLE Goal 1: Improve <grade levels> student achievement in <*curricular area*>	
#1: Strategy Name: *Teacher professional development.*	*1. Use of Professional Learning Teams for student data analysis.* *2. Professional development to improve teacher content knowledge.*
#2: Strategy Name: *Added technology to curriculum.*	*1. Ongoing job embedded coaching in instructional technology.* *2. Benchmark assessments for students.* *3. Pre and Post survey of students' technology skills.*

• Create an implementation timeline for each goal using the model shown below. Costs may be broken down by actions or by strategies (as shown by the partially completed example below). In-kind/matching costs are not required, but should be included if they will be used for this program. When grant funds are listed, the dollar amount is required. If in-kind/matching costs are included, please cite their purpose, source, and amount for example, In-kind Professional Development, $25,000.

EXAMPLE Category	Start date	End date	Point of contact	Costs
Goal 1: Title	Improve <grade levels> student achievement in <*curricular area*>			
Strategy 1, Action 1				Grant: In-kind/Matching:
Strategy 1, Action 2				
Strategy 2, Action 1				Grant: In-kind/Matching:
Strategy 2, Action 2				
Strategy 2, Action 3				

Section D: Project Evaluation (30 points)

• Include (1) the fidelity of program implementation, (2) formative or process evaluation activities that provide information to guide program improvement, and (3) a summative evaluation to assess how the outcomes have addressed the academic needs. The evaluation should help shape the project from inception. The evaluation plan must:

1. Pose questions, in each of the three areas above that the evaluation will answer.
2. Describe the data and the data collection process (including multiple sources).
3. Describe how the data will be analyzed.
4. Identify who will conduct the evaluation.
5. Indicate what resources will be expended in the evaluation.
6. Explain how the data will be used, particularly to inform decisions involving curriculum and instruction at the classroom, school, and/or district levels.

Notes:

—The evaluation concept should provide a broad framework regarding the data collection sources, the available resources, and how the data will inform decisions involving curriculum and instruction at the classroom, school and/or system levels.
—Data collection instruments should include standardized forms (such as validated surveys and assessment protocols) wherever possible.
—Grantees must disaggregate data at the school level for the military student population.
—Grantees will be required to submit quarterly reports regarding evaluation activities.
—Three percent of total grant funds must be spent on a third-party/external evaluator.

Section E: Management Plan (10 points)

• Indicate the Project Director who will be responsible for day-to-day management of the grant.
• Provide information on the qualifications of all project leader(s), including their role and responsibilities relative to the strategies and actions, and estimated time commitment to the project.
• The third-party evaluator's qualifications and roles should be briefly described.
• Append résumés of project leaders—each being 1–2 pages in length. If the third-party evaluator has not been determined, then his or her role and qualifications should be described.

Section F: Budget Narrative and Sustainability (10 points)

• Align budget with proposed project plan, goals, and activities.
• Provide a narrative justification for the items included in the proposed budget.
• Describe existing resources and other support the LEA expects to receive for the proposed project.
• Identify how project leaders will track budget expenditures.
• Describe how project activities will be sustained after completion of the grant period.

Notes:

—For budgeting purposes, the grant years are:
Year 1: June 1, 2012–August 31, 2013.
Year 2: September 1, 2013–August 31, 2014.
Year 3: September 1, 2014–August 31, 2015.

Review and Selection Process

MCASP applications are peer reviewed according to the evaluation criteria listed above. Applications may receive a maximum score of 110 points.

Narrative (15-page maximum)	Points
Needs Assessment	10
Project Goals	10
Project Plan	30
Project Evaluation	30
Management	10
Budget Narrative and Sustainability	10
Priority 1: High concentration of military dependent students	5
Priority 2: New applicants	5
Total	110

Decisions to fund a grant are based on:

- Strengths and weaknesses of the application as identified by peer reviewers
- Availability of funds
- Equitable distribution of awards in terms of geography, Branches of Service, repeat awardees, or other factors.

Required Application Components

Applications must include the required 10 application components.

Cover page: Cover page must include contact information, names of military installations served, focus areas, enrollment data, and authorized signature.

Abstracts: Both a 50-word and a 200-word abstract are required. Abstracts must provide a clear overview of the project's purpose, design, and goals. Both abstracts may be placed on the same page in the application.

Table of Contents: Proposals should include an accurate Table of Contents.

Project Narrative: The project narrative must not exceed 15 pages (excluding supporting documents and appendices) and should include all sections listed under the Evaluation Criteria section of this announcement.

Supporting documents: Supporting documents should include needs assessment data, résumés of key personnel, and bibliography. Letters of support may be included.

Evaluation design matrix: The evaluation design matrix illustrates goals and strategies as outlined in the evaluation plan.

Budget Table: Proposals must include a detailed budget.

SF 424: Standard Form 424—Application for Federal Assistance is required.

SF 424A: Standard Form 424A—Budget Information for Non-Construction Programs is required. All sections on this form must be completed. Totals should match the detailed budget.

SF 424B: Standard Form 424B—Assurances for Non-Construction Programs is required.

Certifications: Applicants must complete the Certification Regarding Lobbying form and the Certification regarding Debarment, Suspension, and Other Responsibility Matters (*www.grants.gov*).

Funding Requirements

Cost sharing: Cost sharing/matching funds are not required in this program.

Indirect costs: No grant funds may be allocated to administrative or indirect costs. Indirect costs are those incurred for a common or joint purpose benefiting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. For further information, see OMB Circular A–87 –Attachment B.

Personnel: Up to 25 percent of Federal funds may be allocated to full-time equivalent (FTE) positions. However, proposed budgets that exceed 25 percent for FTE personnel may be considered. The term, *full-time equivalent* (FTE), usually refers to fully benefited positions. For grant purposes, the funding category, *Personnel,* includes FTE and non-FTE positions/costs. Examples of non-FTE personnel costs include stipends for teachers, wages to afterschool tutors, and costs for substitute teachers. FTE and non-FTE positions must be clearly delineated on the detailed budget (Appendix C).

Fringe benefits: Although fringe benefits for grant-funded FTE positions are an allowable cost, no grants funds may be allocated for administrative or indirect costs. Fringe Benefits are defined as costs in the form of employer contributions or expenses for social security; employee life, health, unemployment, and worker's compensation insurance (except as indicated in OMB Circular A–87 (Attachment B, No. 22)), and other similar benefits for employees expected to work solely on this grant.

Equipment: ''Equipment means tangible, nonexpendable, personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. A grantee may use its own definition of equipment provided that such definition would at least include all equipment defined above.'' See DoD 3210.6–Rs 33.3 for additional information.

Evaluation: DoDEA requires that at least three percent of grant funds will be spent on a third-party evaluator. The third-party evaluator may not be a current employee of the LEA.

Grant meeting: In the Year 1 budget, LEAs must include $3,000 for the project director and the third-party evaluator to attend a two-day meeting, which is expected to occur in September 2012. Any funds not expended for the meeting may be realigned in the grant for other grant usage. **Note:** An LEA located outside the continental United States may wish to budget additional funds.

Submission Requirements

Applications are due Friday, April 13, 2012, by 11:59 p.m. (Eastern Time). All applications must be submitted electronically through *www.grants.gov* by the deadline. Applications received after the deadline will not be considered.

The following standards should be followed:

- A page is 8.5″ x 11″, one side only, with 1″ margins at the top, bottom, and both sides.
- Single space all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a 12-point font; titles may be larger; charts may use a 10-point font.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) may not be accepted.

Proposal Compliance

Failure to adhere to deadlines to be specified in the forthcoming application may result in proposal rejection. Any proposal received after the exact time and date specified for receipt will not be considered. DoDEA, at its sole discretion, may accept a late proposal if it determines that no advantage has been conferred and that the integrity of the grants process will not be compromised.

Dated: March 1, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–5456 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2012–0007]

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to Delete a System of Records.

SUMMARY: The Department of the Air Force is deleting a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on April 6, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Charles J. Shedrick, Department of the Air Force Privacy Office, Air Force Privacy Act Office, Office of Warfighting Integration and Chief Information officer, ATTN: SAF/XCPPI, 1800 Air Force Pentagon, Washington, DC 20330–1800 or at 202–404–6575.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The Department of the Air Force proposes to delete one system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: March 1, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletion:

F036 AFPC D

SYSTEM NAME:

Correction of Military Records System (June 11, 1997, 62 FR 31793).

REASON:

Documents are no longer required to be maintained by any office within the Air Force Personnel Center (AFPC). The Secretary of the Air Force (SAF), Air Force Board for the Correction of Military Records (BCMR) is responsible for maintaining documentation. These records are covered by F036 SAFPC A, Military Records Processed by the Air Force Correction Board (May 7, 1999, 64 FR 24605). Case files are maintained for 75 years, and then destroyed. F036 AFPC D, Correction of Military Records System (June 11, 1997, 62 FR 31793) therefore can be deleted.

[FR Doc. 2012–5443 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Board of Visitors, Defense Language Institute Foreign Language Center

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended) and 41 CFR 102–3.150, the Department of Defense announces that the following Federal advisory committee meeting will take place:

Name of Committee: Board of Visitors, Defense Language Institute Foreign Language Center.

Date: March 21, 2012.

Time of Meeting: Approximately 8 a.m. through 4:30 p.m. Please allow extra time for gate security for both days.

Location: Defense Language Institute Foreign Language Center and Presidio of Monterey (DLIFLC & POM), Weckerling Center, Monterey, CA 93944.

Purpose of the Meeting: The purpose of the meeting is to provide a general orientation to the DLIFLC mission and functional areas. In addition, the meeting will involve administrative matters, ACCJC interactions, and a review of previous BoV recommendations.

Agenda: Summary—March 21—The Board will be briefed on DLIFLC mission and functional areas. Board administrative details to include parent committee introduction, board purpose, operating procedures review, and oath. The Board may also meet members of the ACCJC as required, and will review past BoV recommendations.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis. No member of the public attending open meetings will be allowed to present questions from the floor or speak to any issue under consideration by the Board. Although open to the public, gate access is required no later than five work days prior to the meeting. Contact the Committee's Designated Federal Officer, below, for gate access procedures.

Committee's Designated Federal Officer or Point of Contact: Mr. Detlev Kesten, ATFL–APO, Monterey, CA 93944, *Detlev.kesten@us.army.mil,* (831) 242–6670.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public may submit written statements to the Board of Visitors of the Defense Language Institute Foreign Language Center in response to the agenda. All written statements shall be submitted to the Designated Federal Officer of the Board of Visitors of the Defense Language Institute Foreign Language Center, and this individual will ensure that the written statements are provided to the membership for their consideration. Written statements should be sent to: Attention: DFO at ATFL–APO, Monterey, CA 93944 or faxed to (831) 242–6495. Statements must be received by the Designated Federal officer at least five work days prior to the meeting. Written statements received after this date may not be provided to or considered by the Board of Visitors of the Defense Language Institute Foreign Language Center until its next meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Detlev Kesten, ATFL–APO, Monterey, CA 93944, *Detlev.kesten@us.army.mil,* (831) 242–6670.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2012–5508 Filed 3–6–12; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2012–0005]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to Delete Fifteen Systems of Records.

SUMMARY: The Department of the Army is deleting fifteen systems of records notices in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on April 6, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905 or by calling (703) 428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The Department of the Army proposes to delete fifteen systems of records notices from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletions are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: March 2, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletions:

A0001a AHRC

Office Visitor/Commercial Solicitor Files (February 23, 2004, 69 FR 8183).

REASON:

As of January 2010 records covered by this System of Records notice are no longer collected by Army Human Resource Command, have met the approved NARA retention schedule; therefore the notice can be deleted.

A0060–20 USFK

Ration Control/Blackmarket Monitoring Files (August 24, 1999, 64 FR 46186).

REASON:

The records have been transferred under SORN A0600–8, USKF (February 7, 2001, 66 FR 9298) and are under the same NARA disposition. Therefore, system of records notice A0060–20, USFK can be deleted.

A0001 DAPE

Personnel Locator/Organizational Roster/Telephone Directory (February 22, 1993, 58 FR 10002).

REASON:

The records in this system will now be covered under system of records notice DPR 39, DoD Personnel Accountability and Assessment System (March 24, 2010, 75 FR 14141). The records will be retained and have the same NARA approved retention for DPR 39 DoD. Therefore, the system of records notice can be deleted.

A0210–130 DALO

Laundry Accounting Files (April 12, 1999, 64 FR 17641).

REASON:

The program using this system of records notice is no longer active. The approved NARA retention schedule for the records stored in the system have been met, and therefore, the system of records notice can be deleted.

A0001b AHRC

Unit Administrative Military Personnel Records (January 6, 2004, 69 FR 790).

REASON:

The program using this system of records notice has been deactivated and has met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0015–34 AHRC

Army Civilian/Military Service Review Board (January 6, 2004, 69 FR 790).

REASON:

The program has been discontinued at Army Human Resource Command, records have met the approved NARA retention schedule and are no longer collected; therefore, the system of records notice can be deleted.

A0065 AHRC

Postal and Mail Service System (January 6, 2004, 69 FR 790).

REASON:

The program has been discontinued at Army Human Resource Command, records have met the approved NARA retention schedule and are no longer collected; therefore, the system of records notice can be deleted.

A0210–190 AHRC

Individual Gravesite Interment Files (January 6, 2004, 69 FR 790).

REASON:

The program has been discontinued at Army Human Resource Command, and records have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–104b AHRC

Official Military Personnel Record (August 18, 2004, 69 FR 51271).

REASON:

The program has been discontinued at Army Human Resource Command, and records have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–104g AHRC

Career Management Individual and Dual Component Personnel Files (January 6, 2004, 69 FR 790).

REASON:

The program has been discontinued at Army Human Resource Command, and records have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–14 AHRC

Uniformed Services Identification Card (January 6, 2004, 69 FR 790).

REASON:

The records are no longer collected at Army Human Resource Command, and have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–1a AHRC

Emergency Data Files (January 6, 2004, 69 FR 790).

REASON:

The records are no longer collected at Army Human Resource Command, and have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–1b AHRC

Line of Duty Investigations (January 6, 2004, 69 FR 790).

REASON:

The program at Army Resource Command (AHRC) has been discontinued and records are no longer collected and have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–22 AHRC

Military Awards Case File (January 6, 2004, 69 FR 790).

REASON:

The program at Army Resource Command (AHRC) has been discontinued and records are no longer collected and have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

A0600–8–22j AHRC

Cold War Recognition System (January 6, 2004, 69 FR 790).

REASON:

The system at Army Human Resource Command (AHRC) has been deactivated and records are no longer collected and have met the approved NARA retention schedule; therefore, the system of records notice can be deleted.

[FR Doc. 2012–5516 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2012–0004]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to delete thirteen systems of records.

SUMMARY: The Department of the Army is deleting thirteen systems of records notices in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on April 6, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905 or by calling (703) 428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The Department of the Army proposes to delete thirteen systems of records notices from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletions are not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: March 1, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0600–8–23 AHRC

Standard Installation/Division Personnel System (SIDPERS) (December 11, 2006, 71 FR 71537).

REASON:

The system at Army Human Resource Command (AHRC) has been deactivated and records will be transferred to the National Personal Records Center to meet the approved NARA retention of 75 years, then destroyed. Therefore, the system of records notice can be deleted.

A0600o AHRC

Army Career and Alumni Program (ACAP XXI) (January 6, 2004, 69 FR 790).

REASON:

The program has been discontinued and records have met the approved NARA retention schedule and are no longer needed and have been destroyed. Therefore, the system of records notice can be deleted.

A0601–100 AHRC

Officer Appointment Files (January 6, 2004, 69 FR 790).

REASON:

The files are no longer collected at Army Human Resource Command, records have met the approved NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

A0601–210 AHRC

Eligibility Determination Files (February 23, 2004, 69 FR 8183).

REASON:

The files are no longer collected at Army Human Resource Command, records have met the approved NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

A0601–280a AHRC

Qualitative Management Program Appeal File (January 6, 2004, 69 FR 790).

REASON:

The files are no longer collected at Army Human Resource Command and have been transferred to the National Personnel Records Center in the military members Master Personnel Record Jacket (MPRJ); therefore, the system of records notice can be deleted.

A0601–280b AHRC

Selective Reenlistment Bonus (January 6, 2004, 69 FR 790).

REASON:

The files are no longer collected at Army Human Resource Command, records have met the approved NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

A0602 AHRC–ARI

Behavioral and Social Sciences Research Project Files (January 6, 2004, 69 FR 790).

REASON:

The files are no longer collected at Army Human Resource Command, records have met the approved NARA retention schedule and destroyed; therefore, the system of records notice can be deleted.

A0608 AHRC

Personal Affairs Files (January 6, 2004, 69 FR 790).

REASON:

The files are no longer collected at Army Human Resource Command, have met the approved NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

A0614–200 AHRC

Classification and Reclassification of Soldiers (August 18, 2004, 69 FR 51271).

REASON:

The program files are no longer collected at Army Human Resource Command, have met the approved NARA retention schedule and destroyed; therefore, the system of records notice can be deleted.

A0635–200 AHRC

Separations: Administrative Board Proceedings (August 18, 2004, 69 FR 51271).

REASON:

The program has been discontinued and records have met the NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

A0635–40 AHRC

Temporary Disability Retirement Master List (TDRL) (August 18, 2004, 69 FR 51271).

REASON:

The program files are no longer collected at Army Human Resource Command, have met the approved NARA retention schedule and destroyed in January 2010; therefore, the system of records notice can be deleted.

A0635–5 AHRC

Separation Transaction Control/Records Transfer System (August 18, 2004, 69 FR 51271).

REASON:

The program has been deactivated at Army Human Resource Command, records have met the approved NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

A0635a AHRC

Combat-Related Special Compensation Files (June 5, 2008, 73 FR 32002).

REASON:

The files are no longer being collected at Army Human Resource Command, have met the approved NARA retention schedule and have been destroyed; therefore, the system of records notice can be deleted.

[FR Doc. 2012–5444 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2012–0004]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Department of the Navy proposes to add a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on April 6, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Patterson, Department of the Navy, DNS–36, 2000 Navy Pentagon, Washington, DC 20350–2000 or call at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on March 1, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: March 2, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NM07251–1

SYSTEM NAME:

Department of the Navy Mass Transportation Benefit Program.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List (SNDL) that is available as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department of Navy (DON) military and civilian personnel applying for and/or obtaining a mass transportation subsidy for commuting to and from work.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, last four of Social Security Number (SSN), DoD ID Number, point-to-point commuting expenses, commuting distance, type of mass transit used, home address, organizational affiliation of the individual, funding appropriation for benefit, office work number, email address, duty/work address, transit authority card number, and usage from benefit provider.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 5 U.S.C. 7905, Programs to encourage commuting by means other than single-occupancy motor vehicles; DoD Instruction 1000.27, Mass Transportation Benefit Program (MTBP); E.O. 12191, Federal facility ridesharing program; E.O. 13150, Federal Workforce Transportation; and E.O. 9397 (SSN), as amended.

PURPOSE(S):

To manage the DON Mass Transportation Benefit Program for DON military and civilian personnel applying for and in receipt of mass transit subsidies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the benefit provider for purposes of administering the DON Mass Transportation Benefit Program and/or verifying the eligibility of individuals to receive a fare subsidy pursuant to the transportation benefit program operated by the DON.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Department of the Navy's compilation of systems of records notices apply to this system of records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Individual's name and last four of Social Security Number (SSN).

SAFEGUARDS:

Records are stored in a secured area accessible only to authorized personnel. Records are accessed by the custodian of the record system and by persons responsible for using or servicing the system, who are properly screened and have a need-to-know. Computer hardware is located in controlled areas with access limited to authorized personnel.

RETENTION AND DISPOSAL:

Destroy applications of employees no longer in the program, superseded applications, certification logs, vouchers, spreadsheets and other forms used to document the disbursement of subsidies when six (6) years and three (3) months old.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Assistant Secretary of the Navy for Financial Management and Comptroller, Office of Financial Operations, 720 Kennon Street SE., Bldg. 36, Room 115, Washington Navy Yard, DC 20374–5025.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Deputy Assistant Secretary of the Navy for Financial Management and Comptroller, Office of Financial Operations, 720 Kennon Street SE., Bldg 36, Room 115, Washington Navy Yard, DC 20374–5025.

Written requests for information should contain the full name of the individual and last four of Social Security Number (SSN).

The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Deputy Assistant Secretary of the Navy for Financial Management and Comptroller, Office of Financial Operations, 720 Kennon Street SE., Bldg 36, Room 115, Washington Navy Yard, DC 20374–5025.

Written requests for information should contain the full name of the individual, last four of Social Security Number (SSN), and include the name and number of this system of records notice and be signed by the individual.

The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.

CONTESTING RECORD PROCEDURES:

The Department of Navy's rules for accessing records, for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2012–5488 Filed 3–6–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Disability and Rehabilitation Research Project; National Data and Statistical Center for the Burn Model Systems

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information:

Proposed priority—National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Disability and Rehabilitation Research Project (DRRP)—National Data and Statistical Center for the Burn Model Systems.

CFDA Number: 84.133A–4.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for a DRRP that will serve as a National Data and Statistical Center for the Burn Model Systems. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2012 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved outcomes for individuals with burn injury.

DATES: We must receive your comments on or before April 6, 2012.

ADDRESSES: Address all comments about this notice to Lynn Medley, U.S. Department of Education, 400 Maryland Avenue SW., Room 5140, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: *lynn.medley@ed.gov.* You must include ''Proposed Priority for the National Data and Statistical Center for the Burn Model Systems'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Lynn Medley. Telephone: (202) 245–7338 or by email: *Lynn.Medley@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This notice of proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *www.ed.gov/about/offices/list/osers/nidrr/policy.html.*

Through the implementation of the Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps;

(5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2012 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award for this priority. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in Room 5140, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities; to develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities; and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: Research, training, demonstration, development, dissemination, utilization, and technical assistance.

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

Proposed Priority: This notice contains one proposed priority.

National Data and Statistical Center for the Burn Model Systems

Background:

It is estimated that there are more than 1 million burn injuries in the United States each year. Approximately 450,000 of these burn injuries are treated annually in emergency departments, hospital outpatient clinics, free-standing urgent care centers, or private physician offices, and 45,000 are severe enough to require hospitalization (Esselman et al., 2006; American Burn Association, 2011).

In recent years, burn survivability has increased dramatically. This improvement in survival rates has brought rehabilitation issues to the forefront of care for burn survivors and led to increased demands for research-based knowledge about the post-acute experiences and needs of burn survivors (Esselman et al., 2006).

NIDRR created the Burn Injury Rehabilitation Model Systems of Care (BMS) in 1994 to provide leadership in rehabilitation, a key component of exemplary burn care, and to advance the research base of rehabilitation services for burn survivors. NIDRR currently funds 4 BMS Centers throughout the United States. Each center provides a coordinated system of burn injury care to individuals who sustain a burn injury, including emergency care, acute care management, comprehensive inpatient rehabilitation, and long-term interdisciplinary community re-entry services. In addition, the BMS Centers conduct research to generate new knowledge about the natural course of burn injury and rehabilitation treatment and outcomes following burn injury.

The BMS Centers have developed a longitudinal database that contains information on approximately 4,700 people injured with burns since 1994 (BMS Database). Since 1994, BMS Centers have collected longitudinal data on database participants at six months, twelve months, and twenty-four months after injury. In the 2006–2011 funding cycle, the BMS Centers conducted a pilot test to determine the feasibility of also collecting longitudinal data at five years and ten years after injury. As a result of this pilot test, NIDRR has decided to extend longitudinal data collection for 2012–2017 to include all participants and to occur every fifth year after injury (five years, ten years, fifteen years, etc.).

The BMS Database is emerging as an important source of information about the characteristics and life course of individuals with burn injury and can be used to examine specific outcomes of burn injury. NIDRR seeks to build upon this database by continuing to fund a National Data and Statistical Center for the BMS (National BMS Data Center), which maintains the BMS Database, improves the quality of information that is entered into it, and facilitates the use of the data by BMS researchers and the public.

The BMS Database is a collaborative project in which all of the BMS Centers are required to participate. The data for the BMS Database are collected by the BMS Centers. The directors of the BMS Centers, including the National BMS Data Center, in consultation with NIDRR, determine the parameters of the BMS Database, including the number and type of variables to be examined, the criteria for including individuals with burn injuries in the BMS Database, and the frequency and timing of data collection.

The specifications of the BMS Database as it is currently implemented (including information about the number of database participants, the variables in the database, and the longitudinal intervals at which data are collected) can be obtained from the BMS Database Coordination Center at *http://bms-dcc.ucdenver.edu/.*

References:

American Burn Association (2011). Burn Incidence and Treatment in the United States: 2011 Fact Sheet. *http://www.ameriburn.org/resources_factsheet.php.*

Esselman, P., Thombs, B., Fauerbach, J.,

Magyar-Russell, G., Price, M. (2006). Burn Rehabilitation State of the Science Review. *American Journal of Physical Medicine and Rehabilitation,* 85 (2006) 383–413.

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for the establishment of a National Data and Statistical Center for the Burn Model Systems (National BMS Data Center). The National BMS Data Center must advance medical rehabilitation by increasing the rigor and efficiency of scientific efforts to assess the experiences and outcomes of individuals with burn injury. To meet this priority, the National BMS Data Center's research and technical assistance must be designed to contribute to the following outcomes:

(a) Maintenance of a national longitudinal database (BMS Database) for data submitted by each of the Burn Model Systems Centers (BMS Centers). This database must provide confidentiality, quality control, and data-retrieval capabilities, using cost-effective technology and user-friendly interfaces.

(b) High-quality, reliable data in the BMS Database. The National BMS Data Center must contribute to this outcome by providing training and technical assistance to BMS Centers on subject retention and data collection procedures, data entry methods, and appropriate use of study instruments, and by monitoring the quality of the data submitted by the BMS Centers.

(c) High-quality data collected from database participants of all racial/ethnic backgrounds. The National BMS Data Center must contribute to this outcome by providing knowledge, training, and technical assistance to the BMS Centers on culturally appropriate methods of longitudinal data collection and participant retention.

(d) Rigorous research conducted by BMS Centers and investigators from outside of the BMS network who are analyzing data from the BMS Database. The National BMS Data Center must contribute to this outcome by making statistical and other methodological consultation available for research projects that use the BMS Database, as well as site-specific research projects being conducted by the BMS Centers.

(e) Improved efficiency of the BMS Database operations. The National BMS Data Center must pursue strategies to achieve this outcome, such as collaborating with the National Data and Statistical Center for Traumatic Brain Injury Model Systems, the National Data and Statistical Center for Spinal Cord Injury Model Systems, and the Model Systems Knowledge Translation Center (MSKTC).

(f) Improved reports for the public from the BMS Database. The National BMS Data Center must produce a report based on the BMS Database at least once a year that provides basic demographic, epidemiological, and outcome information about burn survivors. The National BMS Data Center must collaborate with the MSKTC to distribute information about burn injury and burn rehabilitation to the public through a NIDRR-funded Web site and other media.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available

techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are taking this regulatory action only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. This proposed priority would generate new knowledge through research and development. Another benefit of this proposed priority is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRP would generate, disseminate, and promote the use of new information that would improve the options for individuals with disabilities to perform activities of their choice in the community.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: March 2, 2012.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2012–5565 Filed 3–6–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Disability and Rehabilitation Research Project; Traumatic Brain Injury Model Systems Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information:

Proposed priority—National Institute on Disability and Rehabilitation Research—Disability and Rehabilitation Research Projects and Centers Program—Disability and Rehabilitation Research Project—Traumatic Brain Injury Model Systems Centers.

CFDA Number: 84.133A–5.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for Disability and Rehabilitation Research Projects (DRRPs) to serve as Traumatic Brain Injury Model Systems (TBIMS) Centers. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2012 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved outcomes for individuals with traumatic brain injury.

DATES: We must receive your comments on or before April 6, 2012.

ADDRESSES: Address all comments about this notice to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., Room 5133, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: *marlene.spencer@ed.gov.* You must include ''*Proposed Priority for Traumatic Brain Injury Model Systems (TBIMS) Centers*'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Marlene Spencer. Telephone: (202) 245–7532 or by email: *marlene.spencer@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

This notice of proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *http://www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf.*

Through the implementation of the Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2012 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award for this priority. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific

requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in Room 5133, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, are to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: Research, training, demonstration, development, dissemination, utilization, and technical assistance.

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

PROPOSED PRIORITY:

This notice contains one proposed priority.

Traumatic Brain Injury Model Systems (TBIMS) Centers.

Background:

The Centers for Disease Control and Prevention (CDC) report that each year in the United States at least 1.7 million people sustain a traumatic brain injury (TBI). Of these, approximately 52,000 die, 275,000 are hospitalized, and 1.3 million are treated and released from emergency departments (CDC, 2010; Faul, Xu, Wald, & Coronado, 2010). These estimates do not include those individuals who sustained a TBI and did not seek medical care, those seen only in private doctors' offices, or those treated in military or veteran health care facilities. The leading causes of TBI are falls (35.2 percent), motor vehicle/traffic collisions (17.3 percent), struck by/against events (16.5 percent), and assaults (10 percent) (Faul et al., 2010). Blasts are a leading cause of TBI among active duty military personnel serving in war zones (Defense and Veterans Brain Injury Center, 2011a). The number of TBIs experienced by members of the U.S. Armed Forces between the start of 2000 and the end of the second quarter of 2011 is reported to be 220,430 (Defense and Veterans Brain Injury Center, 2011b).

Common disabilities resulting from TBI include problems with cognition, sensory processing, communication, and behavioral or mental health; and some TBI survivors develop long-term medical complications (National Institute of Neurological Disorders and Stroke, 2011). Direct medical costs and indirect costs such as lost productivity associated with TBI totaled an estimated $76.5 billion in the United States in 2010 (CDC, 2011). Despite the prevalence of TBI and the disabilities that often follow, less than 20 percent of the management guidelines for TBI are supported by either Class I (prospective, randomized, controlled trials with masked outcome assessment, in a representative population) or Class II (prospective matched group cohort study in a representative population with masked outcome assessments) research evidence (Maas, Roozenbeek, & Manley, 2010).

The Traumatic Brain Injury Model Systems Centers (TBIMS Centers) program was created by NIDRR in 1987 to demonstrate the benefits of a coordinated system of neurotrauma and rehabilitation care and to conduct innovative research on all aspects of care for those who sustain TBI. The mission of the TBIMS Centers is to improve the lives of persons who experience TBI, and of their families and communities, by creating and disseminating new knowledge about the natural course of TBI and rehabilitation treatment and outcomes following TBI. The influence of the program was expanded in the current grant cycle through numerous TBI interagency initiatives with the U.S. Departments of Veterans Affairs and Defense, the National Institute of Neurological Disorders and Stroke, the Centers for Disease Control and Prevention, and the Defense and Veterans Brain Injury Center.

NIDRR currently funds 16 TBIMS Centers, which are located throughout the United States. These centers provide comprehensive systems of brain injury care to individuals who sustain TBI and conduct TBI research, including clinical research and the analysis of standardized data in collaboration with other related projects. Since 1989, the TBIMS Centers have collected and contributed information on common data elements for a centralized TBIMS database, which is maintained through a NIDRR-funded grant for a National Data and Statistical Center for the TBIMS Centers. (Additional information on the TBIMS database can be found at *http://tbindsc.org*). The TBI National Data and Statistical Center for the TBIMS Centers coordinates data collection, manages the TBIMS database, and provides statistical support to the model systems projects. As of December, 2011, TBIMS Centers have contributed 10,631 cases to the TBIMS database, with follow-up data available to date for 8,136 participants at 1 year post injury; 6,889 at 2 years post injury; 4,425 at 5 years post injury; 1,834 at 10 years post injury; and 484 at 20 years post injury.

Through this priority, we seek to fund new TBIMS Centers that will continue to provide a coordinated, multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. These services would span the continuum of treatment from acute care through community re-entry. Under this priority, TBIMS Centers would engage in initiatives and new approaches and maintain close working relationships with other governmental and non-profit institutions and organizations to coordinate scientific efforts, encourage joint planning, and promote the

interchange of data and reports among TBI researchers. As part of these cooperative efforts, TBIMS Centers would participate in collaborative research projects that range from pilot research to more extensive studies.

A committee consisting of the individual TBIMS project directors has, since its inception, guided the TBIMS Centers program. This group meets bi-annually in Washington, DC, and, in consultation with NIDRR, develops and oversees the policies of the TBIMS Centers. NIDRR intends to form such a committee with the project directors awarded grants under this proposed priority.

References:

Centers for Disease Control and Prevention. (2010). *Injury prevention & control: Traumatic brain injury.* Retrieved December 2, 2011, from *www.cdc.gov/traumaticbraininjury/statistics.html.*

Centers for Disease Control and Prevention. (2011). *Severe traumatic brain injury.* Retrieved December 2, 2011, from *www.cdc.gov/TraumaticBrainInjury/severe.html.*

Defense and Veterans Brain Injury Center. (2011a). *TBI facts: What is a traumatic brain injury?* Retrieved December 2, 2011, from *www.dvbic.org/TBI---The-Military/TBI-Facts.aspx.*

Defense and Veterans Brain Injury Center. (2011b). DOD worldwide numbers for TBI—Archives. Retrieved December 2, 2011, from *www.dvbic.org/Archive-of-DoD-Numbers-for-TBI.aspx.*

Faul, M., Xu, L., Wald, M.M., & Coronado, V.G. (2010). *Traumatic brain injury in the United States: Emergency department visits, hospitalizations, and deaths 2002–2006.* Atlanta (GA): Centers for Disease Control and Prevention, National Center for Injury Prevention and Control.

Maas, A.I.R., Roozenbeek, R., & Manley, G.T. (2010). Clinical trials in traumatic brain injury: Past experience and current developments. *Neurotherapeutics,* 7, 115–126.

National Institute of Neurological Disorders and Stroke (NINDS). (2011, April). *Traumatic brain injury: Hope through research.* Bethesda, MD: National Institutes of Health. NIH Publication No. 02–2478. Retrieved December 2, 2011, from *www.ninds.nih.gov/disorders/tbi/detail_tbi.htm.*

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for the funding of Traumatic Brain Injury Model Systems (TBIMS) Centers under the Disability and Rehabilitation Research Projects (DRRP) program. The TBIMS Centers must provide comprehensive, multidisciplinary services to individuals with traumatic brain injury (TBI) and conduct research that contributes to the development of evidence-based rehabilitation interventions and clinical and practice guidelines.

For purposes of this priority, the term *traumatic brain injury* or *TBI* is defined as damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness or post-traumatic amnesia due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Both penetrating and non-penetrating wounds that fit this criteria are included, but, primary anoxic encephalopathy is not.

The TBIMS Centers must generate new knowledge that can be used to improve outcomes of individuals with TBI in one or more domains identified in NIDRR's currently approved Long Range Plan, published in the **Federal Register** on February 15, 2006 (71 FR 8165): Health and function, community living and participation, technology, and employment. Each TBIMS Center must contribute to this outcome by:

(a) Providing a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. The system must encompass a continuum of care, including emergency medical services, acute care services, acute medical rehabilitation services, and post-acute services;

(b) Continuing the assessment of long-term outcomes of individuals with TBI by enrolling at least 35 subjects per year into the TBIMS database, following established protocols for the collection of enrollment and follow-up data on subjects (found at *http://www.tbindsc.org/*);

Note: TBIMS Centers will be funded at varying amounts up to the maximum award based on the numbers of TBIMS database participants from whom TBIMS Centers must collect follow-up data. TBIMS Centers that have previously been TBIMS grantees with large numbers of database participants will receive more funding within the specified range than TBIMS Centers with fewer participants, as determined by NIDRR after applicants are selected for funding. Applicants must include in their budgets specific estimates of their costs for follow-up data collection. Funding will be determined individually for each successful applicant, up to the maximum allowed, based upon the documented workload associated with the follow-up data collection, other costs of the grant, and the overall budget of the research project.

(c) Proposing and conducting at least one, but no more than two, site-specific research projects to test innovative approaches to treating TBI or to assess outcomes of individuals with TBI. Site-specific research projects must focus on outcomes in one or more domains identified in the Plan: Health and function, community living and participation, technology, and employment;

Note: Applicants who propose more than two site-specific research projects will be disqualified.

(d) Participating as research collaborators in at least one module project. Module projects are research collaborations with one or more TBIMS Centers on topics of mutual interest and expertise. Such module projects must be carried out as part of the TBIMS Centers' activities. They must not be part of a current TBIMS Multi-Site Collaborative Project, which the Department funded under a separate priority (see the notice inviting applications, published in the **Federal Register** on February 1, 2008 (73 FR 6162) and the associated notice of final priority, published in the **Federal Register** on February 1, 2008 (73 FR 6132).

Note: Applicants should not propose a specific module project in their application. While all TBIMS Centers grantees are required to participate as research collaborators in at least one module project, they are not required to develop any module project on their own. Immediately following the announcement of awards under this priority, TBIMS Centers that are interested in proposing module projects may identify module topics, identify potential collaborators from among the other TBIMS Centers, and propose research protocols for the potential modules. At the first TBIMS Centers Project Directors' meeting, Project Directors will review, discuss, and decide upon specific module projects to implement. NIDRR staff will facilitate this post-award discussion and negotiation among TBIMS Centers grantees. Once these module projects are agreed upon by the Project Directors, each TBIMS Center must participate in at least one of them.

(e) Demonstrating, in its application, its capacity to successfully engage in multi-site collaborative research on TBI. This capacity includes access to research participants, the ability to maintain data quality, and the ability to adhere to research protocols;

(f) Spending at least 15 percent of its annual budget on participating in a module project, as described in paragraph (d) of this priority;

(g) Spending $5,000 of its total budget towards the costs of a state-of-the-science conference to be planned and executed with input and participation by the TBIMS Centers;

(h) Coordinating with the NIDRR-funded Model Systems Knowledge Translation Center (MSKTC; *http://www.msktc.org/*) to provide scientific results and information for

dissemination to clinical and consumer audiences;

(i) Addressing the needs of individuals with TBI, including individuals from one or more traditionally underserved populations; and

(j) Ensuring that the input of individuals with TBI is used to shape TBIMS research.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563:

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are taking this regulatory action only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. This proposed priority would generate new knowledge through research and development. Another benefit of this proposed priority is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRP would generate, disseminate, and promote the use of new information that would improve the options for individuals with disabilities to perform activities of their choice in the community.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

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at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: March 2, 2012.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2012–5576 Filed 3–6–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Disability and Rehabilitation Research Project; Burn Model Systems Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information:

Proposed priority—National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Disability and Rehabilitation Research Project (DRRP)—Burn Model Systems Centers.

CFDA Number: 84.133A–3.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for DRRPs that will serve as Burn Model Systems (BMS) Centers. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2012 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved outcomes for individuals with burn injury.

DATES: We must receive your comments on or before April 6, 2012.

ADDRESSES: Address all comments about this notice to Lynn Medley, U.S. Department of Education, 400 Maryland Avenue SW., Room 5140, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: *lynn.medley@ed.gov.* You must include ''Proposed Priority for Burn Model Systems (BMS) Centers'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Lynn Medley. Telephone: (202) 245–7338 or by email: *Lynn.Medley@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

This notice of proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *http://www2.ed.gov/legislation/FedRegister/other/2006–1/021506d.pdf.*

Through the implementation of the Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2012 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award for this priority. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 5140, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, are to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: Research, training, demonstration, development, dissemination, utilization, and technical assistance.

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

Proposed Priority:

This notice contains one proposed priority.

Burn Model Systems (BMS) Centers.

Background:

The American Burn Association (ABA) reports that 450,000 persons in the United States receive medical treatment for burn injuries annually (ABA, 2011). Of these, 3,500 die and 45,000 are hospitalized. Of those hospitalized, 25,000 are treated in hospitals with burn centers. With advances in early medical response to burn injuries and advances in infection control, survival rates of those incurring large burns have significantly increased (ABA, 2011b; Soman, Greenhalgh, & Palmieri, 2010). For those who survive, there are often significant challenges that affect their functional outcomes. Physical challenges may include severe contractures, joint deformities, neurologic and musculosketal problems, scarring, pain, and fatigue (Dewey, Richard, & Parry, 2011; Gabriel, 2011; Schneider, Holavanahalli, Helm, Goldstein, & Kowalske, K., 2006; Schneider & Qu, 2011). Psychological challenges may include posttraumatic stress, depression, and anxiety (Fauerbach et al., 2007; Ullrich, Askay, & Patterson, 2009; Wiechman, 2011). Psychosocial and environmental factors make community integration, including return to school and work, difficult (Esselman, 2011; Schneider, Bassi, & Ryan, 2009). Improvements in survival rates have highlighted the need for comprehensive rehabilitation treatment teams that provide a continuum of coordinated services from admission to the burn unit to assistance with community reintegration, and a combined focus on physical and psychological rehabilitation (Esselman & Kowalske, 2011; Richard et al., 2008).

The Burn Injury Model Systems centers (BMS Centers) program was created by NIDRR in 1994 to provide leadership in rehabilitation as a key component of exemplary burn care and to advance the research base on effective rehabilitation services for burn survivors. The mission of the BMS Centers is to improve the lives of persons who experience burn injury and their families by creating and disseminating new knowledge about the natural course of burn injury and rehabilitation treatment and outcomes following burn injury. NIDRR currently funds 4 BMS Centers throughout the United States. Each BMS Center provides a coordinated system of burn injury care to individuals who sustain a burn injury and conducts burn research, including clinical research and the analysis of standardized data in collaboration with other BMS Centers. Since 1998, the BMS Centers have collected and contributed information on common data elements for a centralized BMS database, which is maintained through a NIDRR-funded grant for a National Data and Statistical Center for the BMS. (Additional information on the BMS database can be found at *http://bms-dcc.ucdenver.edu/*). The National Data and Statistical Center for the BMS coordinates data collection among the BMS Centers, manages the BMS database, and provides statistical support to the BMS Centers. As of December, 2011, BMS Centers have contributed 4,917 cases to the BMS database, with follow up data available for 3,419 participants at 6-months post injury; 2,998 at 1 year post injury; and 2,481 at 2 years post injury. During the 2007–2012 grant cycle, data collection was extended to include information from participants at 5 and 10 years post injury.

Through this priority, we seek to fund new BMS Centers that will continue to provide a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with burn injury. These services would span the continuum of treatment from acute care through community re-entry. Under this priority, BMS Centers would engage in initiatives and new approaches and maintain close working relationships with other governmental and non-profit institutions and organizations to coordinate scientific efforts, encourage joint planning, and promote the interchange of data and reports among burn injury researchers.

A committee consisting of the individual BMS project directors has, since its inception, guided the BMS Centers program. This group meets annually in Washington, DC and at the annual ABA meeting. They also meet by teleconference throughout the year. NIDRR intends to form such a committee with the project directors awarded grants under this proposed priority.

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Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for the funding of Burn Model Systems centers (BMS Centers). The BMS Centers must provide comprehensive, multidisciplinary services to individuals with burn injury and conduct research that contributes to evidence-based rehabilitation interventions and clinical and practice guidelines. The BMS Centers must generate new knowledge that can be used to improve outcomes of

individuals with burn injury in one or more domains identified in NIDRR's currently approved Long Range Plan, published in the **Federal Register** on February 15, 2006 (71 FR 8166): Health and function, participation and community living, technology, and employment. Each BMS Center must contribute to this outcome by—

(a) Providing a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with burn injury, including but not limited to physical, psychological, and community reintegration needs. The system must encompass a continuum of care, including emergency medical services, acute care services, acute medical rehabilitation services, and post-acute services;

(b) Continuing the assessment of long-term outcomes of individuals with burn injury by enrolling at least 30 subjects per year into the BMS database, and collecting follow-up data on all subjects enrolled in the database at 6 months, and at 1, 2, 5, and 10 years post injury (as is being done in the current grant cycle) and extending the assessment to every five years thereafter, following established protocols for the collection of enrollment and follow-up data on subjects;

Note: BMS Centers will be funded at varying amounts up to the maximum award based on the numbers of BMS database participants from whom BMS Centers must collect follow-up data. BMS Centers that have previously been BMS grantees with large numbers of database participants will receive more funding within the specified range than BMS Centers with fewer participants, as determined by NIDRR after applicants are selected for funding. Applicants must include in their budgets specific estimates of their costs for follow-up data collection. Funding will be determined individually for each successful applicant, up to the maximum allowed, based upon the documented workload associated with the follow-up data collection, other costs of the grant, and the overall budget of the research project.

(c) Proposing and conducting at least one, but no more than two, site-specific research projects to test innovative approaches to treating burn injury or to assess outcomes of individuals with burn injury. Site-specific research projects must focus on outcomes in one or more domains identified in the Plan: health and function, community living and participation, technology, and employment;

Note: Applicants who propose more than two site-specific research projects will be disqualified. Site-specific research projects may include collaborating entities as needed for execution of the research project.

(d) Coordinating with the NIDRR-funded Model Systems Knowledge Translation Center (MSKTC; *http://www.msktc.org/*) to provide scientific results and information for dissemination to clinical and consumer audiences;

(e) Spending $5,000 of its total budget toward the costs of a state-of-the-science conference, which will be planned and executed with input and participation by the BMS Centers;

(f) Addressing the needs of individuals with burn injuries, including individuals from one or more traditionally underserved populations; and

(g) Ensuring that the input of individuals with burn injuries is used to shape BMS research activities.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register.** The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the invitational priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the **Federal Register.** We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register.**

Executive Orders 12866 and 13563:

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extentpracticable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation,

including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are taking this regulatory action only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. This proposed priority would generate new knowledge through research and development. Another benefit of this proposed priority is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRP would generate, disseminate, and promote the use of new information that would improve the options for individuals with disabilities to perform activities of their choice in the community.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: March 2, 2012.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2012–5568 Filed 3–6–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Electricity Subsector Cybersecurity Risk Management Process Guideline

AGENCY: Office of Electricity Delivery and Energy Reliability, Department of Energy.

ACTION: Notice of public comment.

SUMMARY: The Department of Energy (DOE) invites public comment on DOE's intent to publish the Electricity Subsector Cybersecurity Risk Management Process guideline. The guideline describes a risk management process that is targeted to the specific needs of electricity sector organizations. The objective of the guideline is to build upon existing guidance and requirements to develop a flexible risk management process tuned to the diverse missions, equipment, and business needs of the electric power industry.

DATES: Comments must be received on or before Thursday, April 5, 2012.

ADDRESSES: Written comments may be submitted to Matthew Light, U.S. Department of Energy, Office of Electricity Delivery and Energy Reliability, 1000 Independence Ave. SW., Washington, DC 20585; Fax 202–586–2623; Email: *matthew.light@hq.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Request for additional information should be directed to Matthew Light at *matthew.light@hq.doe.gov,* phone 202–316–5115.

SUPPLEMENTARY INFORMATION: DOE invites public comment on DOE's intent to publish a guidance document entitled: Electricity Subsector Cybersecurity Risk Management Process Guideline. The primary goal of this guideline is to describe a risk management process that is targeted to the specific needs of electricity sector organizations. The objective of the guideline is to build upon existing guidance and requirements to develop a flexible risk management process tuned to the diverse missions, equipment, and business needs of the electric power industry.

The Electricity Subsector Cybersecurity Risk Management Process guideline was developed by the DOE, in collaboration with the National Institute of Standards and Technology (NIST), the North American Electric Reliability Corporation (NERC), and representatives from both the public and private sector. The NIST Special Publication 800–39, Managing Information Security Risk provides the foundational methodology for this document.

The Electricity Sector Cybersecurity Risk Management Process Guideline is available for review at: *http://energy.gov/oe/downloads/draft-cybersecurity-risk-management-process-rmp-guideline*.

Authority: Homeland Security Presidential Directive 7 (HSPD–7).

Issued at Washington, DC, on March 1, 2012.

Patricia A. Hoffman,

Assistant Secretary, Electricity Delivery and Energy Reliability.

[FR Doc. 2012–5512 Filed 3–6–12; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL ENERGY REGULATORY COMMISSION

[Project No. 14364–000]

Three Sisters Irrigation District; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, Protests, Recommendations, and Terms and Conditions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Conduit Exemption.

b. *Project No.:* 14364–000.

c. *Date filed:* February 8, 2012.

d. *Applicant:* Three Sisters Irrigation District.

e. *Name of Project:* Three Sisters Irrigation District Hydroelectric Project.

f. *Location:* The proposed Three Sisters Irrigation District Hydroelectric Project would be located on the north pipe of the Three Sisters Irrigation District's Main Canal Pipeline in Deschutes County, Oregon. The land on which all the project structures is owned by the applicant.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Marc Thalacker, P.O. Box 2230, Sisters, OR 97759, phone (541) 549–8815.

i. *FERC Contact:* Kelly Houff, (202) 502–6393, *Kelly.Houff@ferc.gov.*

j. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

k. *Deadline for filing responsive documents:* Due to the small size of the proposed project, as well as the resource agency consultation letters filed with the application, the 60-day timeframe specified in 18 CFR 4.34(b) for filing all comments, motions to intervene, protests, recommendations, terms and conditions, and prescriptions is shortened to 30 days from the issuance date of this notice. All reply comments filed in response to comments submitted by any resource agency, Indian tribe, or person, must be filed with the Commission within 45 days from the issuance date of this notice.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under *http://www.ferc.gov/docs-filing/efiling.asp.* The Commission strongly encourages electronic filings.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, it must also serve a copy of the document on that resource agency.

l. *Description of Project:* The Three Sisters Irrigation District Hydroelectric Project would consist of: (1) An intake pipe approximately 40 feet in length; (2) a powerhouse containing one proposed generating unit with an installed capacity of 700 kilowatts; (3) a discharge pipe approximately 50 feet in length; and (4) appurtenant facilities. The applicant estimates the project would have an average annual generation of 3,400 megawatt-hours.

m. This filing is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, P–14364, in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for review and reproduction at the address in item h above.

n. Development Application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a competing development application. A notice of intent must be served on the applicant(s) named in this public notice.

p. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

q. All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''COMMENTS'', ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and seven copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Office of Energy Projects, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: March 1, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5533 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG12–35–000.

Applicants: Stephentown Spindle, LLC.

Description: Notice of Self-Certification as an Exempt Wholesale Generator of Stephentown Spindle, LLC.

Filed Date: 2/29/12.

Accession Number: 20120229–5099.

Comments Due: 5 p.m. ET 3/21/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2025–001; ER11–4655–001.
Applicants: Louis Dreyfus Energy Services L.P., Rensselaer Cogeneration LLC.
Description: Notice of Change in Status of Louis Dreyfus Energy Services L.P., *et al.*
Filed Date: 2/29/12
Accession Number: 20120229–5126.
Comments Due: 5 p.m. ET 3/21/12.
Docket Numbers: ER10–2776–003.
Applicants: Wells Fargo Commodities, LLC.
Description: Notice of Non-Material Change in Status of Wells Fargo Commodities, LLC.
Filed Date: 2/29/12.
Accession Number: 20120229–5079.
Comments Due: 5 p.m. ET 3/21/12.
Docket Numbers: ER12–458–003.
Applicants: Quantum Choctaw Power, LLC.
Description: Quantum Choctaw Power Compliance Filing—Clone—Clone to be effective 2/14/2012.
Filed Date: 2/29/12
Accession Number: 20120229–5073.
Comments Due: 5 p.m. ET 3/21/12.
Docket Numbers: ER12–513–001.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance Filing per 1/30/2012 Order in ER12–513 to be effective 1/31/2012 to be effective 1/31/2012.
Filed Date: 2/28/12.
Accession Number: 20120228–5145.
Comments Due: 5 p.m. ET 3/20/12.
Docket Numbers: ER12–513–002.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance Filing per 1/30/2012 Order in ER12–513 to be effective 6/30/2012 to be effective 6/30/2012.
Filed Date: 2/28/12.
Accession Number: 20120228–5171.
Comments Due: 5 p.m. ET 3/20/12.
Docket Numbers: ER12–1085–001.
Applicants: Florida Power & Light Company.
Description: FPL Amendment to Schedule 10 *re* Offer of Settlement and Agreement to be effective 10/1/2011.
Filed Date: 2/21/12.
Accession Number: 20120221–5274.
Comments Due: 5 p.m. ET 3/13/12.
Docket Numbers: ER12–1174–000.
Applicants: Cross Border Energy LLC.
Description: Baseline Tariff to be effective 11/21/2009.
Filed Date: 2/29/12.
Accession Number: 20120229–5080.
Comments Due: 5 p.m. ET 3/21/12.
Docket Numbers: ER12–1175–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Request for Waiver of Midwest Independent Transmission System Operator, Inc.
Filed Date: 2/23/12.
Accession Number: 20120223–5120.
Comments Due: 5 p.m. ET 3/15/12.

Take notice that the Commission received the following electric securities filings:
Docket Numbers: ES12–24–000
Applicants: AEP Appalachian Transmission Company, Inc., AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Oklahoma Transmission Company, Inc., AEP Southwestern Transmission Company, Inc., AEP West Virginia Transmission Company, Inc.
Description: Application under Section 204 of the Federal Power Act of AEP Appalachian Transmission Company, Inc., *et al* for Authorization to Issue Securities.
Filed Date: 2/28/12.
Accession Number: 20120228–5199.
Comments Due: 5 p.m. ET 3/20/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 29, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–5479 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP12–417–000.
Applicants: Viking Gas Transmission Company.
Description: LMCRA—Spring 2012 to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5022.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–418–000.
Applicants: Columbia Gulf Transmission Company.
Description: TRA 2012 to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5023.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–419–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Antero 2 to Tenaska 423 Capacity Release Negotiated Rate Agreement Filing to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5024.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–420–000.
Applicants: Gulf South Pipeline Company, LP.
Description: HK 37731 to Spark 39604 Capacity Release Negotiated Rate Agreement Filing to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5025.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–421–000.
Applicants: Gulf South Pipeline Company, LP.
Description: HK 37731 to Texla 39606 Capacity Release Negotiated Rate Agreement Filing to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5026.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–422–000.
Applicants: Gulf South Pipeline Company, LP.
Description: HK 37731 to Sequent 39605 Capacity Release Negotiated Rate Agreement Filing to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5027.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–423–000.
Applicants: Columbia Gas Transmission, LLC.
Description: EPCA 2012 to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5028.
Comments Due: 5 p.m. ET 3/12/12.
Docket Numbers: RP12–424–000.
Applicants: Dauphin Island Gathering Partners.
Description: Negotiated Rates 2012–02–29 to be effective 3/1/2012.

Filed Date: 2/29/12.
Accession Number: 20120229–5061.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–425–000.
Applicants: Northwest Pipeline GP.
Description: NWP Fuel Factor Filing, Effective April 1, 2012 to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5065.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–426–000.
Applicants: TWP Pipeline LLC.
Description: Annual FRP Filing to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5067.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–427–000.
Applicants: Millennium Pipeline Company, LLC.
Description: Annual Retainage Adjustment Mechanism Filing to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5071.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–428–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Tenaska 38581–2 Amendment to Negotiated Rate Agreement Filing to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5107.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–429–000.
Applicants: Columbia Gas Transmission, LLC.
Description: RAM 2012 to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5130.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–430–000.
Applicants: Central Kentucky Transmission Company.
Description: Annual RAM Filing—2012 to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5137.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–431–000.
Applicants: Millennium Pipeline Company, LLC.
Description: Annual Operational Purchases and Sales Filing to be effective N/A.
Filed Date: 2/29/12.
Accession Number: 20120229–5162.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–432–000.
Applicants: Transwestern Pipeline Company, LLC.
Description: 2012 TW Settlement Fuel Filing to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5166.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–433–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Negotiated Rate Filing-Shell to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5191.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–434–000.
Applicants: Kern River Gas Transmission Company.
Description: 2012 Daggett Surcharge to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5220.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–435–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Negotiated Rate Filing-CIMA to be effective 3/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5221.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–436–000.
Applicants: Dominion Cove Point LNG, LP.
Description: DCP—2012 Annual EPCA to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5227.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–437–000.
Applicants: Dominion Cove Point LNG, LP.
Description: DCP—2012 Annual Fuel Retainage to be effective 4/1/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5243.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–438–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Negotiated Rate Service Agreement Filing—WGL to be effective 3/28/2012.
Filed Date: 2/29/12.
Accession Number: 20120229–5269.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–439–000.
Applicants: TransColorado Gas Transmission Company LLC.
Description: TransColorado Gas Transmission Company LLC's Annual Fuel Gas Reimbursement Percentage Report.
Filed Date: 2/29/12.
Accession Number: 20120229–5301.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–440–000.
Applicants: Stingray Pipeline Company, L.L.C.
Description: Filed Date: 2/29/12.
Accession Number: 20120229–5309.
Comments Due: 5 p.m. ET 3/12/12.

Docket Numbers: RP12–441–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Annual Electric Power Tracker Filing effective April 1, 2012 to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5034.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–442–000.
Applicants: ANR Pipeline Company.
Description: ANR Pipeline Company submits tariff filing per 154.403(d)(2): Fuel Filing 2012 to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5037.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–443–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Fuel Filing—Eff. April 1, 2012 to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5038.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–444–000.
Applicants: Williston Basin Interstate Pipeline Company.
Description: 2012 Annual Fuel and Electric Power Reimbursement to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5039.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–445–000.
Applicants: Dauphin Island Gathering Partners.
Description: Dauphin Island Gathering Partners submits tariff filing per 154.403: Storm Surcharge 2012 to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5051.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–446–000.
Applicants: Texas Eastern Transmission, LP.
Description: Update GTC Section 3.18 to Delete Contract 830089 to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5068.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–447–000.
Applicants: Cimarron River Pipeline, LLC.
Description: Cimarron River Pipeline, LLC submits tariff filing per 154.403(d)(2): Fuel Tracker 2012 to be effective 4/1/2012.
Filed Date: 3/1/12.
Accession Number: 20120301–5071.
Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–448–000.
Applicants: PostRock KPC Pipeline, LLC.

Description: KPC Fuel Reimbursement Adjustment, to be effective 4/1/2012.

Filed Date: 3/1/12.

Accession Number: 20120301–5072.

Comments Due: 5 p.m. ET 3/13/12.

Docket Numbers: RP12–449–000.

Applicants: MarkWest Pioneer, L.L.C.

Description: MarkWest Pioneer—Quarterly FRP Filing to be effective 4/1/2012.

Filed Date: 3/1/12.

Accession Number: 20120301–5073.

Comments Due: 5 p.m. ET 12/13/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings.

Docket Numbers: RP12–128–005.

Applicants: Algonquin Gas Transmission, LLC.

Description: Docket RP12–128 Compliance Filing #2 to be effective 12/2/2011.

Filed Date: 2/22/12.

Accession Number: 20120222–5072.

Comments Due: 5 p.m. ET 3/8/12.

Docket Numbers: RP12–359–002.

Applicants: CenterPoint Energy Gas Transmission Company.

Description: CEGT LLC—February 2012 Negotiated Rate Filing—Amended 2–22–12 to be effective 2/1/2012.

Filed Date: 2/22/12.

Accession Number: 20120222–5109.

Comments Due: 5 p.m. ET 3/8/12.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 1, 2012.

Nathaniel J. Davis, Sr.

Deputy Secretary

[FR Doc. 2012–5475 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–39–000]

Seminole Electric Cooperative, Inc. and Florida Municipal Power Agency v. Florida Power Corporation; Notice of Complaint

Take notice that on February 29, 2012, pursuant to sections 206, 306, and 309 of the Federal Power Act (FPA), 16 U.S.C. 824e, 825e, and 825h, and Rule 206 of the Federal Energy Regulatory Commission's (FERC or Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2011), Seminole Electric Cooperative, Inc. and Florida Municipal Power Agency (Complainants) filed a formal complaint against Florida Power Corporation (Respondent) alleging that the return on equity (ROE) in Respondent's transmission formula rate is unjust and unreasonable.

Complainants certify that copies of the complaint were served on the contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on March 20, 2012.

Dated: March 1, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5539 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–40–000]

California Independent System Operator Corporation; Notice of Complaint

Take notice that on February 29, 2012, pursuant to sections 206, 306, and 309 of the Federal Power Act, 16 U.S.C. 824e, 825e, and 825h, and section 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, California Independent System Operator Corporation (Complainant) filed a formal complaint requesting that the Commission modify sections 22.1 and 22.4 of the Transmission Control Agreement (TCA) to revise the standard for a determination of liability or indemnity from an ordinary negligence standard to a gross negligence standard. The Complainant challenges that the TCA would be unjust, unreasonable, and unduly discriminatory without the revisions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission,

888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on March 21, 2012.

Dated: March 1, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5540 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–38–000]

New York Independent System Operator, Inc.; Notice of Petition for Declaratory Order

Take notice that on February 28, 2012, pursuant to Rule 207 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207, New York Independent System Operator, Inc. (NYISO), filed a Petition for Declaratory Order, requesting that the Commission issue an order providing guidance on how the NYISO should recover from its customers the costs assessed pursuant to the Commission's December 30, 2010 Order issued in Docket No. ER11–1844–000.[1] NYISO's petition also seeks declaration that NYISO not be required to pay invoices for charges imposed by Midwest Independent Transmission System Operator, Inc. until after the hearing established in December 30 Order has concluded and a final Commission order has been issued.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on March 29, 2012.

Dated: February 29, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5467 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13583–001—MA]

Crane and Company: Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR part 380 (Order No. 486, 52 FR 47879), the Office of Energy Projects has reviewed the application for exemption from licensing for the Byron Weston Hydroelectric Project, to be located on the East Branch of the Housatonic River, in the Town of Dalton, Berkshire County, Massachusetts, and has prepared an Environmental Assessment (EA). In the EA, Commission staff analyzes the potential environmental effects of the project and concludes that issuing an exemption for the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

A copy of the EA is on file with the Commission and is available for public inspection. The EA may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

For further information, contact Brandon Cherry at (202) 502–8328.

Dated: February 29, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5464 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2310–193]

Pacific Gas and Electric Company; Notice of Extension of Time for Filing of Motions To Intervene and Protests, Comments, Recommendations, Preliminary Terms and Conditions, Preliminary Fishway Prescriptions, Response Comments, and Final License Application Amendments

As stated in a letter dated February 24, 2012, in this proceeding by the Director, Division of Hydropower Licensing, the date for filing of motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions, established by the Commission's notice issued on January 19, 2012,[1] for the Drum-Spaulding Hydroelectric Project No. 2310–193, has been extended to July 31, 2012, with response comments due by September 14, 2012. The filing of final

[1] *Midwest Independent System Operator, Inc.,* 133 FERC ¶ 61,275 (2010) (December 30 Order).

[1] Notice of Application Accepted for Filing, Soliciting Motions to Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions.

license application amendments has been extended to June 18, 2012.

Dated: February 29, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5535 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2266–102]

Nevada Irrigation District; Notice of Extension of Time for Filing of Motions To Intervene and Protests, Comments, Recommendations, Preliminary Terms and Conditions, Preliminary Fishway Prescriptions, Response Comments, and Final License Application Amendments

As stated in a letter dated February 24, 2012, in this proceeding by the Director, Division of Hydropower Licensing, the date for filing of motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions, established by the Commission's notice issued on January 19, 2012,[1] for the Yuba-Bear Hydroelectric Project No. 2266–102, has been extended to July 31, 2012, with response comments due by September 14, 2012. The filing of final license application amendments has been extended to June 18, 2012.

Dated: February 28, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5538 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–1171–000]

CWP Energy; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of CWP Energy's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is March 21, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 1, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–5478 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–1170–000]

Imperial Valley Solar Company (IVSC) 1, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Imperial Valley Solar Company (IVSC) 1, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is March 21, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed

[1] Notice of Application Accepted for Filing, Soliciting Motions to Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions.

docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 1, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–5477 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13848–001]

Qualified Hydro 27, LLC; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 13848–001.

c. *Date Filed:* January 4, 2012.

d. *Submitted By:* Qualified Hydro 27, LLC.

e. *Name of Project:* Howard A. Hanson Dam Hydroelectric Project.

f. *Location:* On the Green River, in King County, Washington. The project occupies 5 acres of United States lands administered by the U.S. Bureau of Reclamation.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Ramya Swaminathan, Free Flow Power Corporation, 239 Causeway Street, Suite 300, Boston, MA 02114; (978) 283–2822.

i. *FERC Contact:* Kelly Wolcott at (202) 502–6480; or email at *kelly.wolcott@ferc.gov.*

j. Qualified Hydro 27, LLC filed its request to use the Traditional Licensing Process on January 4, 2012. Qualified Hydro 27, LLC provided public notice of its request on December 28, 2011. In a letter dated March 1, 2012, the Director of the Division of Hydropower Licensing approved Qualified Hydro 27, LLC's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with: (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; (b) NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920; and (c) the Washington State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Qualified Hydro 27, LLC as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act, section 305 of the Magnuson-Stevens Fishery Conservation and Management Act, and section 106 of the National Historic Preservation Act.

m. Qualified Hydro 27, LLC filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCONlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in paragraph h.

o. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: March 1, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5536 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10482–107]

AER NY-Gen, LLC; Eagle Creek Hydro Power, LLC, Eagle Creek Water Resources, LLC, Eagle Creek Land Resources, LLC; Notice of Application for Transfer of License, and Soliciting Comments and Motions To Intervene

On February 24, 2012, AER NY-Gen, LLC (transferor), Eagle Creek Hydro Power, LLC, Eagle Creek Water Resources, LLC, and Eagle Creek Land Resources, LLC (transferees) filed an application for the transfer of license for the Swinging Bridge Hydroelectric Project No. 10482, located on the Mongaup River in Sullivan County, New York.

Applicants seek Commission approval to transfer the license for the Swinging Bridge Hydroelectric Project from the transferor to the transferees.

Applicants' Contact: Transferor: Mr. Joseph Klimaszewski, AER NY-Gen, LLC, P.O. Box 876, East Aurora, NY 14052, (716) 805–1469. Transferees: Mr. Bernard H. Cherry, Eagle Creek Hydro Power, LLC, Eagle Creek Water Resources, LLC, and Eagle Creek Land Resources, LLC, 65 Madison Avenue, Morristown, NJ 07960, (973) 998–8400.

FERC Contact: Patricia W. Gillis (202) 502–8735, *patricia.gillis@ferc.gov.*

Deadline for filing comments and motions to intervene: 15 days from the issuance date of this notice. Comments and motions to intervene may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1) and the instructions on the Commission's Web site under *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original plus seven copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. More information about this project can be viewed or printed on the eLibrary link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–10482) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Dated: February 29, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5468 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14362–000]

AMENICO Green Solutions, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments and Motions To Intervene

On February 8, 2012, AMENICO Green Solutions, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Pittsfield Mill Dam Hydropower Project (Pittsfield Mill Dam Project or project) to be located on Suncook River, in the Town of Pittsfield, Merrimack County, New Hampshire. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) The existing 421-foot-long, 21-foot-high Pittsfield Mill dam, which is owned by the New Hampshire Department of Environmental Services; (2) an existing 20 acre impoundment with 112 acre-feet of storage capacity at the spillway crest elevation of 474.5 feet above mean sea level (MSL); (3) an existing intake structure; (4) an existing 9-foot-diameter, 200-foot-long steel penstock; (5) an existing powerhouse containing an existing 415 kilowatt turbine-generator; (6) an existing 65-foot-long tailrace; (7) a new 200-foot-long transmission line; and (8) appurtenant facilities. The estimated annual generation of the Pittsfield Mill Dam Project would be 2.0 gigawatt-hours (GWH).

Applicant Contact: Mr. Anthony P. Giunta, Manager, AMENICO Green Solutions, LLC, 5 Main Street, Pittsfield, NH 03263; phone: (603) 228–3611.

FERC Contact: John Ramer; phone: (202) 502–8969.

Deadline for filing comments and motions to intervene: 60 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14362–000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: March 1, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5537 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD12–3–018]

Review of Cost Submittals by Other Federal Agencies for Administering Part I of the Federal Power Act

Notice of Technical Conference

In an order issued on October 8, 2004, the Commission set forth a guideline for Other Federal Agencies (OFAs) to submit their costs related to Administering Part I of the Federal Power Act. *Order On Rehearing Consolidating Administrative Annual Charges Bill Appeals And Modifying Annual Charges Billing Procedures,* 109 FERC ¶ 61,040 (2004) (October 8 Order). The Commission required OFAs to submit their costs using the OFA Cost Submission Form. The October 8 Order also announced that a technical conference would be held for the purpose of reviewing the submitted cost forms and detailed supporting documentation.

The Commission will hold a technical conference for reviewing the submitted OFA costs. The purpose of the conference will be for OFAs and licensees to discuss costs reported in the forms and any other supporting documentation or analyses.

The technical conference will be held on March 22, 2012, in Conference Room 3M–1 at the Commission's headquarters, 888 First Street NE., Washington, DC. The technical conference will begin at 2 p.m. (EST).

The technical conference will also be transcribed. Those interested in obtaining a copy of the transcript immediately for a fee should contact the Ace-Federal Reporters, Inc., at 202–347–3700, or 1–800–336–6646. Two weeks after the post-forum meeting, the transcript will be available for free on the Commission's e-library system. Anyone without access to the Commission's Web site or who has questions about the technical conference should contact W. Doug Foster at (202) 502–6118 or via email at *annualcharges@ferc.gov*.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice), (202) 208–8659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

Dated: February 29, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5465 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL12–37–000; QF86–36–006]

PowerSmith Cogeneration Project, LP; Notice of Request for Waiver

Take notice that on February 27, 2012, pursuant to section 292.205(c) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure implementing the Public Utility Regulatory Policies Act of 1978 (PURPA), as amended, 18 CFR 292.205(c), PowerSmith Cogeneration Project, LP (PowerSmith) filed a Request for Waiver, for calendar year 2011, of the operating standard set forth in section 292–205(a)(1) of the Commission's Regulations for the topping-cycle cogeneration facility owned and operated by PowerSmith located in Oklahoma. PowerSmith makes such a request because of a delay in certain major capital improvements.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214).

Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on March 28, 2012.

Dated: February 29, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–5466 Filed 3–6–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Southeastern Power Administration

Proposed Rate Adjustment, Public Forum, and Opportunities for Public Review and Comment for Georgia-Alabama-South Carolina System of Projects

AGENCY: Southeastern Power Administration, DOE.

ACTION: Notice of proposed rate.

SUMMARY: Southeastern Power Administration (Southeastern) proposes to revise existing schedules of rates and charges applicable to the sale of power from the Georgia-Alabama-South Carolina System of Projects effective for a 5-year period, October 1, 2012, through September 30, 2017. Additionally, opportunities will be available for interested persons to review the present rates and the proposed rates and supporting studies, to participate in a public forum and to submit written comments. Southeastern will evaluate all comments received in this process.

DATES: Written comments are due on or before June 5, 2012. A public information and comment forum will be held in Atlanta, Georgia, at 1 p.m. on April 24, 2012. Persons desiring to speak at the forum should notify Southeastern at least seven (7) days before the forum is scheduled, so that a list of forum participants can be prepared. Others may speak if time permits. If Southeastern has not been notified by close of business on April 17, 2012, that at least one person intends to be present at the forum, the forum may be canceled with no further notice.

ADDRESSES: Written comments should be submitted to: Administrator, Southeastern Power Administration, Department of Energy, 1166 Athens Tech Road, Elberton, Georgia 30635–6711. The public information and comment forum for the Georgia-Alabama-South Carolina System of Projects will be at the Renaissance Concourse Atlanta Airport Hotel, One Hartsfield Centre Parkway, Atlanta, GA 30354, Phone: (404) 209–9999.

FOR FURTHER INFORMATION CONTACT: Virgil Hobbs, Assistant Administrator, Finance & Marketing, Southeastern Power Administration, Department of Energy, 1166 Athens Tech Road, Elberton, Georgia 30635, (706) 213–3800.

SUPPLEMENTARY INFORMATION: The Federal Energy Regulatory Commission (FERC) by order issued June 30, 2011 (135 FERC ¶ 62,267), confirmed and approved on a final basis Wholesale Power Rate Schedules SOCO–1–D, SOCO–2–D, SOCO–3–D, SOCO–4–D, ALA–1–M, MISS–1–M, Duke-1–D, Duke-2–D, Duke-3–D, Duke-4–D, Santee-1–D, Santee-2–D, Santee-3–D, Santee-4–D, SCE&G–1–D, SCE&G–2–D, SCE&G–3–D, SCE&G–4–D, Pump-1–A, Pump-2, Regulation-1, and Replacement-1 applicable to Georgia-Alabama-South Carolina System of Projects' power for a period ending September 30, 2015.

Discussion: Existing rate schedules are predicated upon a July 2010 repayment study and other supporting data. A repayment study prepared in February of 2012 shows that existing rates are not adequate to meet repayment criteria. This is due primarily to revenue from stream-flow energy that has been less than previously estimated as a result of below average water conditions, and increased U.S. Army Corps of Engineers Operation & Maintenance expenses.

The revised repayment study shows that a revenue increase of $21,913,000 in fiscal year 2013 and all future years over the current repayment study will result in all costs being repaid within the term of these rate schedules or their service life. Therefore, Southeastern is proposing to revise the existing rates to generate this additional revenue. The rate adjustment is an increase of about ten percent (10%) in the revenue requirement and fifteen percent (15%) in the rates for capacity and energy.

Southeastern is proposing the following rate schedules to be effective for the period from October 1, 2012 through September 30, 2017.

Rate Schedule SOCO–1–E

Available to public bodies and cooperatives in Georgia, Alabama, Mississippi, and Florida to whom power may be wheeled and scheduled pursuant to contracts between the Government and Southern Company Services, Incorporated.

Rate Schedule SOCO–2–E

Available to public bodies and cooperatives in Georgia, Alabama, Mississippi, and Florida to whom power may be wheeled pursuant to contracts between the Government and Southern Company Services, Incorporated. The customer is responsible for providing a scheduling arrangement with the Government.

Rate Schedule SOCO–3–E

Available to public bodies and cooperatives in Georgia, Alabama, Mississippi, and Florida to whom power may be scheduled pursuant to contracts between the Government and Southern Company Services, Incorporated. The customer is responsible for providing a transmission arrangement.

Rate Schedule SOCO–4–E

Available to public bodies and cooperatives in Georgia, Alabama, Mississippi, and Florida served through the transmission facilities of Southern Company Services, Inc. The customer is responsible for providing a scheduling arrangement with the Government and for providing a transmission arrangement.

Rate Schedule ALA–1–N

Available to PowerSouth Energy Cooperative.

Rate Schedule MISS–1–N

Available to the South Mississippi Electric Power Association to whom

power may be wheeled pursuant to contract between the Government and PowerSouth Energy Cooperative.

Rate Schedule Duke-1–E

Available to public bodies and cooperatives in North Carolina and South Carolina to whom power may be wheeled and scheduled pursuant to contracts between the Government and Duke Power Company.

Rate Schedule Duke-2–E

Available to public bodies and cooperatives in North Carolina and South Carolina to whom power may be wheeled pursuant to contracts between the Government and Duke Power Company. The customer is responsible for providing a scheduling arrangement with the Government.

Rate Schedule Duke-3–E

Available to public bodies and cooperatives in North Carolina and South Carolina to whom power may be scheduled pursuant to contracts between the Government and Duke Power Company. The customer is responsible for providing a transmission arrangement.

Rate Schedule Duke-4–E

Available to public bodies and cooperatives in North Carolina and South Carolina served through the transmission facilities of Duke Power Company. The customer is responsible for providing a scheduling arrangement with the Government and for providing a transmission arrangement.

Rate Schedule Santee-1–E

Available to public bodies and cooperatives in South Carolina to whom power may be wheeled and scheduled pursuant to contracts between the Government and South Carolina Public Service Authority.

Rate Schedule Santee-2–E

Available to public bodies and cooperatives in South Carolina to whom power may be wheeled pursuant to contracts between the Government and South Carolina Public Service Authority. The customer is responsible for providing a scheduling arrangement with the Government.

Rate Schedule Santee-3–E

Available to public bodies and cooperatives in South Carolina to whom power may be scheduled pursuant to contracts between the Government and South Carolina Public Service Authority. The customer is responsible for providing a transmission arrangement.

Rate Schedule Santee-4–E

Available to public bodies and cooperatives in South Carolina served through the transmission facilities of South Carolina Public Service Authority. The customer is responsible for providing a scheduling arrangement with the Government and for providing a transmission arrangement.

Rate Schedule SCE&G–1–E

Available to public bodies and cooperatives in South Carolina to whom power may be wheeled and scheduled pursuant to contracts between the Government and South Carolina Electric & Gas Company.

Rate Schedule SCE&G–2–E

Available to public bodies and cooperatives in South Carolina to whom power may be wheeled pursuant to contracts between the Government and South Carolina Electric & Gas Company. The customer is responsible for providing a scheduling arrangement with the Government.

Rate Schedule SCE&G–3–E

Available to public bodies and cooperatives in South Carolina to whom power may be scheduled pursuant to contracts between the Government and South Carolina Electric & Gas Company. The customer is responsible for providing a transmission arrangement.

Rate Schedule SCE&G–4–E

Available to public bodies and cooperatives in South Carolina served through the transmission facilities of South Carolina Electric & Gas Company. The customer is responsible for providing a scheduling arrangement with the Government and for providing a transmission arrangement.

Rate Schedule Pump-1–A

Available to all customers of the Georgia-Alabama-South Carolina System and applicable to energy from pumping operations at the Carters and Richard B. Russell projects.

Rate Schedule Pump-2

Available to public bodies and cooperatives who provide their own scheduling arrangement and elect to allow Southeastern to use a portion of their allocation for pumping.

Rate Schedule Regulation-1

Available to public bodies and cooperatives in Georgia, Alabama, Mississippi, Florida, South Carolina, or North Carolina to whom regulation service is provided pursuant to contracts between the Government and the customer.

Rate Schedule Replacement-1

Available to all customers in the Georgia-Alabama-South Carolina System and applicable to replacement energy.

The proposed rates for capacity, energy, and generation services are as follows:

Capacity	$4.81 per kW per month
Energy	12.33 mills per kWh
Generation Services	$0.12 per kW per month

Under this scenario, 75 per cent of generation revenues are recovered from capacity sales and 25 per cent are recovered from energy sales. These rates are expected to produce an average revenue increase of $22,124,000 million in FY 2013 and all future years.

The rates for transmission, scheduling, reactive supply, and regulation and frequency response apply to all four scenarios and are illustrated in Table 1.

SOUTHEASTERN POWER ADMINISTRATION PROPOSED RATES FOR TRANSMISSION SCHEDULING, REACTIVE, AND REGULATION CHARGES

Rate schedule	Transmission charge $/kW/month	Scheduling charge $/kW/month	Reactive charge $/kW/month	Regulation charge $/kW/month
SOCO–1–E	2.81	0.0806	0.11	0.0483
SOCO–2–E	2.81	.....	0.11	.....
SOCO–3–E	.....	0.0806	.....	0.0483
SOCO–4–E	.....	.....	.....	.....
ALA–1–N	.....	.....	.....	.....
MISS–1–N	2.72	.....	.....	.....
Duke-1–E	1.26	.....	.....	.....

SOUTHEASTERN POWER ADMINISTRATION PROPOSED RATES FOR TRANSMISSION SCHEDULING, REACTIVE, AND REGULATION CHARGES—Continued

Rate schedule	Transmission charge $/kW/month	Scheduling charge $/kW/month	Reactive charge $/kW/month	Regulation charge $/kW/month
Duke-2–E	1.26			
Duke-3–E				
Duke-4–E				
Santee-1–E	1.38			
Santee-2–E	1.38			
Santee-3–E				
Santee-4–E				
SCE&G–1–E	2.12			
SCE&G–2–E	2.12			
SCE&G–3–E				
SCE&G–4–E				
Pump-1–A				
Pump-2				
Regulation-1				0.05
Replacement-1				

The referenced repayment studies are available for examination at 1166 Athens Tech Road, Elberton, Georgia 30635–6711. Proposed Rate Schedules SOCO–1–E, SOCO–2–E, SOCO–3–E, SOCO–4–E, ALA–1–N, MISS–1–N, Duke-1–E, Duke-2–E, Duke-3–E, Duke-4–E, Santee-1–E, Santee-2–E, Santee-3–E, Santee-4–E, SCE&G–1–E, SCE&G–2–E, SCE&G–3–E, SCE&G–4–E, Pump-1–A, Pump-2, Regulation-1, and Replacement-1 are also available.

Dated: February 29, 2012.

Kenneth E. Legg,

Administrator.

[FR Doc. 2012–5511 Filed 3–6–12; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2012–0122; FRL–9340–8]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Chemical Substances Inventory (TSCA Inventory)) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under TSCA sections 5(d)(2) and 5(d)(3), EPA is required to publish in the **Federal Register** a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish in the **Federal Register** periodic status reports on the new chemicals under review and the receipt of notices of commencement (NOC) to manufacture those chemicals. This document, which covers the period from February 1, 2012 to February 17, 2012, and provides the required notice and status report, consists of the PMNs pending or expired, and the NOC to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the specific PMN number or TME number, must be received on or before April 6, 2012.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2012–0122, and the specific PMN number or TME number for the chemical related to your comment, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave. NW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at

http://www.regulations.gov, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Bernice Mudd, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8951; fax number: (202) 564–8955; email address: *mudd.bernice@epa.gov.*

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the PMNs addressed in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Why is EPA taking this action?

EPA classifies a chemical substance as either an ''existing chemical'' or a ''new chemical.'' Any chemical substance that is not on EPA's TSCA Inventory is classified as a ''new chemical,'' while those that are on the TSCA Inventory are classified as an ''existing chemical.'' For more information about the TSCA Inventory go to: *http://www.epa.gov/opptintr/newchems/pubs/inventory.htm.* Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by TSCA section 5 to provide EPA with a PMN, before initiating the activity. Section 5(h)(1) of TSCA authorizes EPA to allow persons, upon application, to manufacture (includes import) or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a), for ''test marketing'' purposes, which is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/opt/newchems.*

Under TSCA sections 5(d)(2) and 5(d)(3), EPA is required to publish in the **Federal Register** a notice of receipt of a PMN or an application for a TME and to publish in the **Federal Register** periodic status reports on the new chemicals under review and the receipt of NOCs to manufacture those chemicals. This status report, which covers the period from February 1, 2012 to February 17, 2012, consists of the PMNs pending or expired, and the NOCs to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

III. Receipt and Status Reports

In Table I. of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this period: The EPA case number assigned to the PMN, the date the PMN was received by EPA, the projected end date for EPA's review of the PMN, the submitting manufacturer/importer, the potential uses identified by the manufacturer/importer in the PMN, and the chemical identity.

TABLE I—14 PMNS RECEIVED FROM 2/01/12 TO 2/17/12

Case No.	Received date	Projected notice end date	Manufacturer/Importer	Use	Chemical
P–12–0173	02/02/2012	05/01/2012	Reichhold, Inc.	(G) Coating additive	(G) Amine salt of hydroxy substituted carboxylic acid, cyclohexyl isocyanate and polyether glycol.
P–12–0174	02/02/2012	05/01/2012	CBI	(G) Rubber adhesive	(G) Polyurethane.

TABLE I—14 PMNS RECEIVED FROM 2/01/12 TO 2/17/12—Continued

Case No.	Received date	Projected notice end date	Manufacturer/ Importer	Use	Chemical
P–12–0175	02/06/2012	05/05/2012	CBI	(G) Dispersant for coatings and inks.	(G) Hydroxyalkanoic acid, compound with aminoheterocycle polymer with hydroxyalkanoic acid, alkyltriamine, lactone, and lactone.
P–12–0176	02/06/2012	05/05/2012	Croda Inc.	(G) Used as a demulsifier for crude oil emulsions in oil field operations.	(G) Alkoxylated phenolic resin.
P–12–0177	02/08/2012	05/07/2012	CBI	(G) Industrial additive	(G) 2-propenoic acid, 2-methyl-, telomer with 2-substituted alkyl alkenoate, 2-mercaptoethanol and sodium 2-methyl-2-[(1-substituted alken-1-yl)nitrogen containing derivative]-amino]-1-substituted alkane (1:1), sodium salt, peroxydisulfuric acid ([(ho)s(o)2]2o2) sodium salt (1:2)-initiated.
P–12–0178	02/13/2012	05/12/2012	CBI	(G) Adhesive for open non-descriptive use.	(G) Polyesterurethane.
P–12–0179	02/13/2012	05/12/2012	CBI	(G) Open, non dispersive use.	(G) Polyurethane dispersion.
P–12–0180	02/13/2012	05/12/2012	CBI	(S) Waterborne acrylic resin for use in coatings.	(G) Aqueous acrylic resin.
P–12–0181	02/15/2012	05/14/2012	Henkel Corporation ..	(S) Cure initiator in adhesive formulations.	(S) Benzamide, N-[(cyclohexylamino)thioxomethyl]-.
P–12–0182	02/15/2012	05/14/2012	CBI	(G) Mining chemical	(G) Amine-modified urea-formaldehyde polymer.
P–12–0183	02/15/2012	05/14/2012	International Specialty Products.	(S) Kinetic hydrate inhibitor.	(S) Acetic acid ethenyl ester, polymer with 1-ethenylhexahydro-2H-azepin-2-one, hydrolyzed.
P–12–0184	02/17/2012	05/16/2012	CBI	(G) Chemical intermediate [destructive use].	(G) Acrylic acid, carbamate, alkyl ester.
P–12–0185	02/17/2012	05/16/2012	CBI	(G) Chemical intermediate [destructive use].	(G) Acrylic acid, carbamate, alkyl ester.
P–12–0186	02/17/2012	05/16/2012	CBI	(G) Chemical intermediate [destructive use].	(G) Acrylic acid, carbamate, alkyl ester.

In Table II. of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs received by EPA during this period: The EPA case number assigned to the NOC, the date the NOC was received by EPA, the projected end date for EPA's review of the NOC, and chemical identity.

TABLE II—25 NOCS RECEIVED FROM 2/1/12 TO 2/17/12

Case No.	Received date	Commencement notice end date	Chemical
P–10–0184	02/03/2012	01/05/2012	(G) Alkyl ethoxylate.
P–10–0209	02/02/2012	01/05/2012	(G) Polyurethane resin.
P–10–0210	02/02/2012	01/05/2012	(G) Polyurethane resin.
P–10–0211	02/02/2012	01/05/2012	(G) Polyurethane resin.
P–10–0212	02/02/2012	01/05/2012	(G) Polyurethane resin.
P–10–0213	02/02/2012	01/05/2012	(G) Polyurethane resin.
P–10–0485	02/08/2012	02/01/2012	(G) Modified fluorinated acrylate.
P–10–0507	02/17/2012	02/13/2012	(S) Starch, oxidized, 2-hydroxy-3-(trimethylammonio)propyl ether, chloride.
P–11–0048	02/08/2012	02/02/2012	(G) Modified fluorinated urethane.
P–11–0227	02/03/2012	01/19/2012	(G) Urethane acrylate.
P–11–0251	02/09/2012	01/19/2012	(G) Cycloaliphatic anhydride polymer with alkyldiol.
P–11–0276	02/06/2012	01/20/2012	(S) 1,5-cyclododecadiene, 10-methoxy-1,5,9-trimethyl- (S) 1,5-cyclododecadiene, 9-methoxy-1,5,10-trimethyl- 1,5-cyclododecadiene, 9-methoxy-1,6,10-trimethyl- 1,5-cyclododecadiene, 9-methoxy-2,5,10-trimethyl.

TABLE II—25 NOCS RECEIVED FROM 2/1/12 TO 2/17/12—Continued

Case No.	Received date	Commencement notice end date	Chemical
P–11–0314	02/10/2012	01/26/2012	(G) Hexanedioic acid, polymer with a-hydro-w-hydroxypoly [oxy (methyl-1,2-ethanediyl)], 1,1'-methylenebis[isocyanatobenzene], and dihydroxydialkyl ether, reaction products with dialkylcarbinol.
P–11–0548	02/16/2012	01/03/2012	(S) Imidodicarbonic diamide, N,N-dibutyl-N',2-bis[4-[(4-isocyanatophenyl)methyl]phenyl]-.
P–11–0566	02/09/2012	02/02/2012	(G) Cycloaliphatic polyacid functional polyester.
P–11–0590	02/03/2012	01/26/2012	(G) Alkyl acrylate, (alkylamino)alkyl ester, telomer with alkyl acrylate and dialkyl- trialkyl-alkoxyaromatic- heterocycloaliphaticketone.
P–11–0605	02/07/2012	02/02/2012	(G) Water based acrylic dispersion.
P–11–0615	02/03/2012	01/31/2012	(G) C_{18} dimer reaction product.
P–11–0621	02/15/2012	12/20/2011	(G) Piperazino based aminoalkylphenone.
P–11–0633	02/01/2012	01/26/2012	(G) Bisalkylidene cycloalkanol, polymers with diisocyanatoalkane polymer, isocyanato-isocyanatoalkyl-alkylcycloalkane, hydroxyalkyl acrylate and polyglycol acrylate.
P–11–0656	02/16/2012	02/06/2012	(S) 2-propenoic acid, 2-methyl-, dodecyl ester, polymer with 2-hydroxyethyl 2-propenoate, .alpha.-(2-methyl-1-oxo-2-propen-1-yl)-.omega.-methoxypoly(oxy-1,2-ethanediyl) and 3-methyl-3-[(2,2,3,3,3-pentafluoropropoxy)methyl]oxetane polymer with tetrahydrofuran mono[2-[(1-oxo-2-propen-1-yl)oxy]ethyl] ether.
P–11–0662	02/03/2012	02/02/2012	(G) Isocyanate-terminated prepolymer.
P–12–0015	02/13/2012	01/24/2012	(G) Substituted aniline, benzenesulfonic acid salt.
P–12–0037	02/02/2012	01/30/2012	(G) Epoxy-novolac resin in non-ionic water emulsion.
P–12–0038	02/02/2012	01/30/2012	(G) Elastomer polyurethane.

If you are interested in information that is not included in these tables, you may contact EPA as described in Unit II. to access additional non-CBI information that may be available.

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Imports, Notice of commencement, Premanufacturer, Reporting and recordkeeping requirements, Test marketing exemptions.

Dated: February 28, 2012.

Chandler Sirmons,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2012–5548 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9644–7]

Good Neighbor Environmental Board; Notification of Public Advisory Committee Teleconference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of Public Advisory Committee Teleconference.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Good Neighbor Environmental Board (GNEB) will hold a public teleconference on March 22, 2012 from 12 p.m. to 5 p.m. Eastern Standard Time. The meeting is open to the public. For further information regarding the teleconference and background materials, please contact Mark Joyce at the number listed below.

Background: GNEB is a federal advisory committee chartered under the Federal Advisory Committee Act, Public Law 92463. GNEB provides advice and recommendations to the President and Congress on environmental and infrastructure issues along the U.S. border with Mexico.

Purpose of Meeting: The purpose of this teleconference is to discuss the Good Neighbor Environmental Board's Fifteenth Report. The report will focus on water infrastructure issues in the U.S.-Mexico border region.

SUPPLEMENTARY INFORMATION: If you wish to make oral comments or submit written comments to the Board, please contact Mark Joyce at least five days prior to the meeting.

General Information: Additional information concerning the GNEB can be found on its Web site at *www.epa.gov/ofacmo/gneb.*

Meeting Access: For information on access or services for individuals with disabilities, please contact Mark Joyce at (202) 564–2130 or email at *joyce.mark@epa.gov.* To request accommodation of a disability, please contact Mark Joyce at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: February 29, 2012.

Mark Joyce,

Acting Designated Federal Officer.

[FR Doc. 2012–5531 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0012; FRL–9337–6]

Pesticide Products; Receipt of Applications To Register New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register new uses for pesticide products containing currently registered active ingredients, pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. EPA is publishing this Notice of such applications, pursuant to section 3(c)(4) of FIFRA.

DATES: Comments must be received on or before April 6, 2012.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number specified below, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through

Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID number specified for the pesticide of interest as shown in the registration application summaries. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: A contact person is listed at the end of each registration application summary and may be contacted by telephone or email. The mailing address for each contact person listed is: Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001 or Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number). If you are commenting on a docket that addresses multiple products, please indicate to which registration number(s) your comment applies. If you are commenting on a docket that addresses multiple products, please indicate to which registration number(s) your comment applies.

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications for New Uses

EPA received applications as follows to register pesticide products containing currently registered active ingredients pursuant to the provisions of section 3(c) of FIFRA, and is publishing this Notice of such applications pursuant to section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

1. *Registration Number:* 100–759. *Docket Number:* EPA–HQ–OPP–2012–0046. *Company name and address:* Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. *Active ingredient:* Fludioxonil. *Proposed Use:* leafy vegetables (except Brassica). *Contact:* Lisa Jones, Registration Division, (703) 308–9424, *jones.lisa@epa.gov.*

2. *Registration Number:* 100–811. *Docket Number:* EPA–HQ–OPP–2012–0045. *Company name and address:* Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. *Active ingredient:* cyprodinil. *Proposed Use:* leafy vegetables (except Brassica). *Contact:* Lisa Jones, Registration Division, (703) 308–9424, *jones.lisa@epa.gov.*

3. *Registration Number:* 100–828. *Docket Number:* EPA–HQ–OPP–2012–0045. *Company name and address:* Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. *Active ingredient:* Cyprodinil. *Proposed Use:* Cardoon, celery, Chinese celery, celtuce, Florence fennel, New Zealand spinach, rhubarb, spinach, spinach vine, swiss chard. *Contact:* Lisa Jones, Registration Division, (703) 308–9424, *jones.lisa@epa.gov.*

4. *Registration Number:* 100–953. *Docket Number:* EPA–HQ–OPP–2012–0046. *Company name and address:* Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. *Active ingredients:* Cyprodinil and Fludioxonil. *Proposed Use:* Cardoon, celery, chinese celery, celtuce, Florence fennel, New Zealand spinach, Rhubarb, spinach, spinach vine, swiss chard. *Contact:* Lisa Jones, Registration Division, (703) 308–9424, *jones.lisa@epa.gov.*

5. *Registration Number:* 100–999, 100–1014. *Docket Number:* EPA–HQ–OPP–2012–0085. *Company name and address:* Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419–8300. *Active ingredient:* Paclobutrazol. *Proposed Use:* Seed treatment for broccoli, cauliflower, and cabbage. *Contact:* Dominic Schuler, Registration Division, (703) 347–0260, *schuler.dominic@epa.gov.*

6. *Registration Numbers:* 352–844, 352–729, 352–728. *Docket Number:* EPA–HQ–OPP–2012–0029. *Company name and address:* DuPont Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, DE 19714. *Active ingredient:* Chlorantraniliprole. *Proposed Uses:* Soybean, Oilseed Crop Group. *Contact:* Jennifer Urbanski, Registration Division, (703) 347–0156, *urbanski.jennifer@epa.gov.*

7. *Registration Numbers:* 10163–282, 10163–283. *Docket Number:* EPA–HQ–OPP–2011–1011. *Company name and address:* Gowan Company, 370 S. Main Street, Yuma, AZ 85364. *Active ingredient:* EPTC. *Proposed Use:* Watermelon; Crop Group 10–10–Citrus Fruit Group; Sunflower subgroup 20B. *Contact:* Emily Hartman, Registration Division, (703) 347–0189, *hartman.emily@epa.gov.*

8. *Registration Number:* 42750–85, 42750–169. *Docket Number:* EPA–HQ–OPP–2012–0010. *Company name and address:* Albaugh Inc., 1525 NE 36th St., Ankeny, IA 50021. *Active ingredient:* Quinclorac. *Proposed Uses:* Rhubarb and berry, low growing, except strawberry, subgroup 13–07H. *Contact:* Maggie Rudick, Registration Division, (703) 347–0257, *rudick.maggie@epa.gov.*

9. *Registration Numbers:* 59639–173, 59639–150, 59639–152. *Docket Number:* EPA–HQ–OPP–2011–0860. *Company name and address:* Valent, U.S.A. Corp, P.O. Box 8025, Walnut Creek, CA 94596–8025. *Active ingredient:* Clothianidin. *Proposed Use:* Strawberry; Crop Group 10–10, Citrus Fruit Group; citrus dried pulp; pistachio; tea. *Contact:* Marianne Lewis, Registration Division, (703) 308–8043, *lewis.marianne@epa.gov.*

10. *Registration Number:* 71512–2, 71512–3. *Docket Number:* EPA–HQ–OPP–2011–0906. *Company name and address:* ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. *Active ingredient:* Cyazofamid. *Proposed Use:* Succulent bean, shelled succulent bean, leafy greens, basil (fresh and dry), tuberous and corm vegetables, fruiting vegetables. *Contact:* Dominic Schuler, Registration Division, (703) 347–0260, *schuler.dominic@epa.gov.*

11. *Registration Numbers:* 66330–38, 66330–39. *Docket Number:* EPA–HQ–OPP–2011–0449. *Company name and address:* Arysta LifeScience North America LLC, 15401 Weston Parkway, Suite 150, Cary, NC 27513. *Active ingredient:* Acequinocyl. *Proposed Uses:* Succulent soybean (edamame); small fruit and berry subgroups 13–07 A, F, and G; succulent bean; cowpea forage; melon subgroup 9A; cucumber; cherry. *Contact:* Autumn Metzger, Registration Division, (703) 305–5314, *metzger.autumn@epa.gov.*

List of Subjects

Environmental protection, Pesticides and pest.

Dated: February 14, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2012–5265 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9644–4]

Notice of Proposed NPDES General Permit; Proposed NPDES General Permit for New and Existing Sources and New Dischargers in the Offshore Subcategory of the Oil and Gas Extraction Category for the Western Portion of the Outer Continental Shelf of the Gulf of Mexico (GMG290000)

Summary: The Regional Administrator of Region 6 today proposes to reissue the National Pollutant Discharge Elimination System (NPDES) General Permit No. GMG290000 for existing and new sources and new dischargers in the Offshore Subcategory of the Oil and Gas Extraction Point Source Category (40 CFR Part 435, Subpart A), located in and discharging to the Outer Continental Shelf offshore of Louisiana and Texas. The discharge of produced water to that portion of the Outer Continental Shelf from Offshore Subcategory facilities located in the territorial seas of Louisiana and Texas is also authorized by this permit.

This draft permit proposes to retain, with certain modifications, the limitations and conditions of the existing 2007 issued permit (2007 permit). The 2007 permit limitations conform with the Oil and Gas Offshore Subcategory Guidelines and contain additional requirements to assess impacts from the discharge of produced water to the marine environment, as required by section 403(c) of the Clean Water Act.

The following major changes to the 2007 permit are proposed as part of the permit reissuance: (1) Define operators for the purpose of this permit, (2) delete New Source Exemption language, (3) add toxicity test requirement for hydrate control fluids, (4) add spill prevention best management practices provision, (5) authorize de minimis discharges caused by subsea safety valve testing, (6) require electronic Notice of Intent (NOI) and discharge monitoring reporting (NetDMR), and (7) establish updated critical dilutions for whole effluent toxicity (WET) limitations for produced water.

Addresses: Comments should be sent to: Ms. Diane Smith, Water Quality Protection Division, U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. Comments may be sent electronically to *smith.diane@epa.gov.*

Dates: Comments must be received by May 7, 2012. Public meetings and hearings on the proposed permit will be

held at the times and places below. The meetings will include a presentation on the proposed permit followed by the opportunity for questions and answers. The public hearings will be held in accordance with the requirements of 40 CFR 124.12. At the public hearing, any person may submit oral or written statements and data concerning the proposed permit. Any person who cannot attend one of the public hearings may still submit written comments, which have the same weight as comments made at the public hearing, through the end of the public comment period.

Date: April 11, 2012.

Time: 6 p.m.–7:30 p.m. for public meeting and 7:30 p.m.–9 p.m. for public hearing.

Place: Houston Marriott South Hobby Airport, Galveston Room, 9100 Gulf Freeway, Houston, TX 77017.

Date: April 12, 2012.

Time: 5:30 p.m.–7 p.m. for public meeting and 7 p.m.–8:30 p.m. for public hearing.

Place: East Bank Regional Library, Jefferson/Napoleon Rooms, 4747 W. Napoleon Ave., Metaire, LA 70001.

For Further Information Contact: Ms. Diane Smith, U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. Telephone: (214) 655–2145. Email address: *smith.diane@epa.gov.* The complete proposed permit, Fact Sheet and a copy of the **Federal Register** notice may also be obtained on the Internet at: *http://www.epa.gov/region6/water/npdes/genpermit/.*

Supplementary Information:

Statutory and Regulatory History

The Clean Water Act (''CWA'') establishes a comprehensive program ''to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'' 33 U.S.C. 1251(a). The CWA also includes the objective of attaining ''water quality which provides for the protection and propagation of fish, shellfish and wildlife and * * * recreation in and on the water.'' 33 U.S.C. 1251(a)(2). To achieve these goals, the CWA requires EPA to control point source discharges of pollutants to Waters of the United States through the issuance of National Pollutant Discharge Elimination System (''NPDES'') permits.

NPDES permits issued for oil and gas exploration, development, and production discharges are required under Section 402(a)(1) of the CWA to include conditions for meeting technology-based effluent limits established under Section 301 and, where applicable, Section 306. Once an effluent limitations guideline or new source performance standard is promulgated in accordance with these sections, NPDES permits issued by the NPDES permitting authorities must incorporate requirements based on such limitations and standards. See 40 CFR 122.44(a)(1). Effluent limitation guidelines for the Offshore Subcategory of the Oil and Gas Extraction Point Source Category are found at 40 CFR part 435, subpart A.

Regulated Entities. EPA intends to use the reissued permit to regulate oil and gas extraction facilities located in the Outer Continental Shelf of the Western Gulf of Mexico, e.g., offshore oil and gas extraction platforms, but other types of facilities may also be subject to the permit. Covered operators would fall primarily under the North American Industrial Classification System (NAICS) 211 and 213 code series (previously the Standard Industrial Classification (SIC) 13 code series). To determine whether your facility, company, business, organization, etc., may be affected by today's action, you should carefully examine the applicability criteria in Part I, Section A.1 of the draft permit. Questions on the permit's application to specific facilities may also be directed to Ms. Smith at the telephone number or address listed above.

Oil Spill Requirements. Section 311 of the Clean Water Act, (CWA or the Act), prohibits the discharge of oil and hazardous materials in harmful quantities. Discharges that are authorized by NPDES permits are excluded from the provisions of Section 311. However, the permit does not preclude the institution of legal action or relieve permittees from any responsibilities, liabilities, or penalties for other, unauthorized discharges of oil and hazardous materials which are covered by Section 311 of the Act.

Ocean Discharge Criteria Evaluation. For discharges into waters of the territorial sea, contiguous zone, or oceans, CWA section 403(c) requires EPA to consider guidelines for determining potential degradation of the marine environment when issuing NPDES permits. These Ocean Discharge Criteria (40 CFR part 125, subpart M) are intended to ''prevent unreasonable degradation of the marine environment and to authorize imposition of effluent limitations, including a prohibition of discharge, if necessary, to ensure this goal'' (45 FR 65942, October 3, 1980). EPA Region 6 previously determined that discharges in compliance with the OCS general permit would not cause unreasonable degradation of the marine environment. EPA had also completed a study of the effects of produced water discharges on hypoxia in the northern Gulf of Mexico and found that these discharges would not have a significant impact. (See Predicted Impacts from Offshore Produced Water Discharges on Hypoxia in the Gulf of Mexico, Limno-Tech, Inc., 2006). Since this reissued permit contains limitations that will protect water quality and in general reduce the discharge of toxic pollutants to the marine environment, the Region finds that discharges authorized by the reissued general permit will not likely cause unreasonable degradation of the marine environment. EPA is proposing to require an industry-wide produced water and drilling fluid characterization study to obtain more representative data to evaluate impacts to water quality.

Marine Protection, Research, and Sanctuaries Act. The Marine Protection, Research and Sanctuaries Act (MPRSA) of 1972 regulates the transportation for dumping of materials into ocean waters and establishes permit programs for ocean dumping. The NPDES permit EPA reissues today does not authorize dumping under MPRSA.

In addition the MPRSA establishes the Marine Sanctuaries Program, implemented by the National Oceanographic and Atmospheric Administration (NOAA), which requires NOAA to designate certain ocean waters as marine sanctuaries for the purpose of preserving or restoring their conservation, recreational, ecological or aesthetic values. Pursuant to the Marine Protection and Sanctuaries Act, NOAA has designated the Flower Garden Banks, an area within the coverage of the OCS general permit, a marine sanctuary. The OCS general permit prohibits discharges in areas of biological concern, including marine sanctuaries. The permit authorizes discharges incidental to oil and gas production from a facility which predates designation of the Flower Garden Banks National Marine Sanctuary as a marine sanctuary. EPA has previously worked extensively with NOAA to ensure that authorized discharges are consistent with regulations governing the National Marine Sanctuary.

National Environmental Policy Act. In connection with its oil and gas leasing programs under the Outer Continental Shelf Lands Act, the Bureau of Ocean Energy Management of the Department of Interior (BOEM) has prepared and published draft environmental impact statements (EIS) on potential impacts of oil and gas operations in the Central and Western Gulf of Mexico for the 2012—2017 period. BOEM published a Notice of Availability of the DRAFT EIS at 76 FR 39435 (December 30, 2011). EPA is

a cooperating agency on BOEM's EIS and intends to use that EIS to fulfill the National Environmental Policy Act obligations for this permit issuance.

Magnuson-Stevens Fisheries Conservation and Management Act. The Magnuson-Stevens Fisheries Conservation and Management Act requires that federal agencies proposing to authorize actions that may adversely affect essential fish habitat (EFH) consult with NMFS. The entire Gulf of Mexico has been designated EFH. EPA intends to adopt the EFH analysis BOEM prepared in the above mentioned Draft EIS for lease sales in the Western and Central Planning Areas (WPA and CPA). BOEM concludes in the Draft EIS that ''Impacts of routine dredging and discharges are localized in time and space and are regulated by Federal and State agencies through permitting processes; therefore, there would be minimal impact to fish resources and essential fish habitat from these routine activities associated with a WPA or CPA proposed action.'' BOEM also concludes that ''If there is an effect of an oil spill on fish resources in the Gulf of Mexico, it is expected to cause a minimal decrease in standing stocks of any population. This is because most spill events would be localized, therefore affecting a small portion of fish populations.'' This permit contains limitations conforming to EPA's Oil and Gas extraction, Offshore Subcategory Effluent Limitations Guidelines at 40 CFR Part 435 and additional requirements assuring that regulated discharges will cause no unreasonable degradation of the marine environment, as required by section 403(c) of the Clean Water Act. This permit also does not authorize spills or any uncontrolled discharges.

Endangered Species Act (ESA). The National Marine Fisheries Service (NMFS) previously concurred with EPA's determination that reissuance of the General Permit for the Outer Continental Shelf of the Western Gulf of Mexico (OCS general permit) was not likely to adversely affect any listed threatened or endangered species or designated critical habitat when the permit was reissued in 1991 and 1998 and when it was modified in 1993 and 2001. When EPA reissued the OCS general permit in 2004, EPA requested written concurrence on EPA's ''may affect but are not likely to adversely affect'' determination from NMFS. In a letter dated July 12, 2004, NMFS provided such concurrence on the 2004 issued OCS general permit. When EPA proposed reissuance of the permit in 2006, EPA found that changes would not decrease the level of protection the permit affords threatened or endangered species. The main changes included new intake structure requirements and more stringent whole effluent toxicity limits based on sub-lethal effects. Since those changes would increase the level of protection, EPA determined that reissuance of the permit was not likely to adversely affect any listed threatened or endangered species or their critical habitat.

EPA is evaluating the effects caused by this permit reissuance action upon the 2004 consultation baseline. EPA will meet its responsibility to fulfill the section 7 of the ESA requirements prior to reissuance of this general permit.

State Water Quality Standards and State Certification. The permit does not authorize discharges to State waters; therefore, the state water quality certification provisions of CWA section 401 do not apply to this proposed action.

Coastal Zone Management Act. EPA determined that activities proposed to be authorized by this reissued permit are consistent with the local and state Coastal Zone Management Plans. The proposed permit and consistency determination was submitted to the State of Louisiana and the State of Texas for interagency review at the time of public notice. Concurrence was received from both Louisiana Department of Natural Resources and Railroad Commission of Texas on the 2007 permit. Both letters of concurrence were dated February 23, 2007. EPA again determines that reissuance of this permit is consistent with the local and state Coastal Zone Management Plans. The proposed permit and consistency determination are submitted to the State of Louisiana and the State of Texas for interagency review at the time of public notice.

Paperwork Reduction Act. The information collection required by this permit will reduce paperwork significantly by implementation of electronic reporting requirements. EPA is working on an electronic notice of intent (eNOI) system so applicants will file their NOIs online. EPA estimates that it takes 10 to 15 minutes to fill up all information required by eNOI for each lease block, and it takes much less time to add, delete, or modify eNOI. EPA will also incorporate an electronic discharge monitoring report (NetDMR) requirement in the permit. The time for NetDMR preparation will be much less than that for paper DMR. The electronic filing systems will also significantly reduce the mailing cost.

Regulatory Flexibility Act. The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq,* requires that EPA prepare a regulatory flexibility analysis for regulations that have a significant impact on a substantial number of small entities. As indicated below, the permit reissuance proposed today is not a ''rule'' subject to the Regulatory Flexibility Act. EPA prepared a regulatory flexibility analysis, however, on the promulgation of the Offshore Subcategory guidelines on which many of the permit's effluent limitations are based. That analysis shows that reissuance of this permit will not have a significant impact on a substantial number of small entities.

Dated February 28, 2012.

William K. Honker,

Acting Director, Water Quality Protection Division, EPA Region 6.

[FR Doc. 2012–5534 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9644–2; CERCLA–04–2012–3763]

Anniston PCB Superfund Site; Anniston, Calhoun County, AL; Correction

AGENCY: Environmental Protection Agency.

ACTION: Notice of Correction to **Federal Register** Posting.

SUMMARY: In the **Federal Register** published on February 27, 2012, 77 FR 11533 (FRL–9637–7), EPA posted a Notice of Amended Settlement concerning the Anniston PCB Superfund Site located in Anniston. The settlement is not an amendment, but a new settlement at this Site. The comment period will remain the same and end on March 28, 2012.

DATES: The Agency will consider public comments on the settlement until March 28, 2012. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlement are available from Ms. Paula V. Painter. Submit your comments by Site name Anniston PCB by one of the following methods:

- *www.epa.gov/region4/superfund/programs/enforcement/enforcement.html.*
- *Email: Painter.Paula@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Paula V. Painter at 404/562–8887.

Dated: February 27, 2012.

Anita L. Davis,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. 2012–5542 Filed 3–6–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011353–037.

Title: The Credit Agreement.

Parties: Crowley Latin America Services, LLC; Dole Ocean Cargo Express; King Ocean Services Limited; Seaboard Marine of Florida, Inc.; and Seaboard Marine Ltd.

Filing Party: Wayne R. Rohde, Esquire; Cozen O'Conner; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment would add Crowley Latin American Services, LLC as a party to the Agreement.

Agreement No.: 012067–006.

Title: U.S. Supplemental Agreement to HLC Agreement.

Parties: BBC Chartering & Logistics GmbH & Co. KG; Beluga Chartering GmbH; Chipolbrok; Clipper Project Ltd.; Hyundai Merchant Marine Co., Ltd.; Industrial Maritime Carriers, L.L.C.; Nordana Line A/S; and Rickmers-Linie GmbH & Cie. KG.

Filing Party: Wade S. Hooker, Esquire; 211 Central Park W.; New York, NY 10024.

Synopsis: The amendment adds Hansa Heavy Lift GmbH as party to the HLC Agreement.

Agreement No.: 012116–001.

Title: NYK/Hanjin/Hyundai/Evergreen-Americas North-South Service Agreement.

Parties: Hanjin Shipping Co., Ltd; Hyundai Merchant Marine Co., Ltd; and Nippon Yusen Kaisha.

Filing Party: David F. Smith, Esquire.; Cozen O'Conner; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment renames the agreement, adds Evergreen Line Joint Services Agreement as party, and updates some of the service references in the agreement.

Agreement No.: 012147–001.

Title: GWF/AGRIEX Space Charter Agreement.

Parties: Great White Fleet (US) Ltd. and Agriculture Investment Export, Inc.

Filing Party: Wade S. Hooker, Esquire, 21 Central Park W.; New York, NY 10024.

Synopsis: The amendment changes the name of Great White Fleet (US) Ltd. to Great White Fleet Liner Services, Ltd.

Agreement No.: 012158.

Title: Altex Chartered/Great White Fleet Slot Charter Agreement.

Parties: Altex Chartered, Inc. and Great White Fleet Liner Services, Ltd.

Filing Party: Tara L. Leiter, Esquire; Blank Rome LLP; 600 New Hampshire Avenue NW.; Washington, DC 20037.

Synopsis: The agreement authorizes Altex Chartered to charter space to Great White Fleet on Altex Chartered's vessels in the trade between South America, Central America and the U.S. East Coast.

Agreement No.: 012159.

Title: Maersk Line/New World Alliance Slot Exchange Agreement.

Parties: A.P. Moller-Maersk A/S trading under the name of Maersk Line; American President Lines, Ltd.; APL Co. Pte, Ltd.; Hyundai Merchant Marine Co., Ltd.; and Mitsui O.S.K. Lines, Ltd.

Filing Party: Wayne R. Rohde, Esquire; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The agreement authorizes the parties to exchange space on their respective services in the trade between the U.S. Atlantic Coast and ports in Panama, the United Kingdom, Germany, the Netherlands and Mediterranean ports in France, Italy and Spain.

Agreement No.: 201179–001.

Title: Lease and Operating Agreement between PRPA and Growmark, Inc.

Parties: Growmark, Inc. and The Philadelphia Regional Port Authority.

Filing Party: Paul D. Coleman, Esquire; Hoppel, Mayer & Coleman; 1050 Connecticut Avenue NW., 10th Floor; Washington, DC 20036.

Synopsis: The amendment provides for an acknowledgement statement that the parties must sign to continue the terms and conditions of the lease.

Dated: March 2, 2012.

By Order of the Federal Maritime Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2012–5564 Filed 3–6–12; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR part 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Asecomer International Corporation dba Interworld Freight Inc. dba Junior Cargo, Inc. dba Intercontinental Lines Corp. (NVO), 8225 NW 80 Street, Miami, FL 33166, Officer: John O. Crespo, President (Qualifying Individual), Application Type: Trade Name Change.

Aslo USA, Corp. (NVO & OFF), 877 SW 149 Court, Miami, FL 33194, Officer: Robert Esquivel, President/Secretary/Treasurer (Qualifying Individual), Application Type: New NVO & OFF License.

Caribbean Forwarding LLC (NVO & OFF), 8730 NW 100th Street, Medley, FL 33178, Officers: Tibisay Tovar, Manager (Qualifying Individual), Doris Rodriguez, Manager, Application Type: New NVO & OFF License.

Clover Systems, LLC dba Clover Marine (NVO & OFF), 1910 NW 97th Avenue, Miami, FL 33172, Officers: Holly A. Rincon, Manager, Luis A. Rincon, Manager (Qualifying Individuals), Application Type: Business Structure Change.

De Well Container Shipping Corp. (NVO), One Cross Island Plaza, Suite 302, Rosedale, NY 11422, Officers: Chang W. Kim, Vice President (Qualifying Individual), Time Yang, Chief Executive Officer, Application Type: QI Change.

Gwinnett Shipping & Receiving, LLC dba Korea Intermodal USA (NVO), 1418 Beaver Ruin Road, Norcross, GA 30093, Officers: Won A. An, Manager (Qualifying Individual), Joon H. An, Member, Application Type: New NVO License.

King Solomon Logistics Inc. (NVO), 135–14 Liberty Avenue, South

Richmond Hill, NY 11419, Officers: Bernard Hollingsworth, President (Qualifying Individual), Veronique Hollingsworth, Secretary/Treasurer, Application Type: New NVO.

Kokusai Soko America, Inc. dba KSAI (OFF), 11105 S. La Cienega Blvd., Los Angeles, CA 90045, Officers: Masahiro Chida, President (Qualifying Individual), Manabu Ishida, Secretary/General Manager, Application Type: QI Change/Trade Name Change.

KY Logistics Inc. (NVO), 167–16 146th Avenue, Suite 203, Jamaica, NY 11434, Officer: Yau Fung Ling, President/Vice President/Secretary/Treasurer (Qualifying Individual), Application Type: New NVO License.

Master Logistics, Inc. (NVO), 9 Woods Lane, Roslyn, NY 11576, Officer: JingLu Tsai, President/Director/Secretary/Treasurer (Qualifying Individual), Application Type: New NVO License.

MNS International Inc (NVO & OFF), 589 Franklin Turnpike, Ridgewood, NJ 07450, Officers: Steven R. Goodglass, Vice President/Treasurer/Director (Qualifying Individual), Mark A. Schriber, President/Secretary/Director, Application Type: New NVO & OFF License.

New Marine Consolidator, Inc. (NVO), 13200 Crossroads Parkway North, Suite 360, City of Industry, CA 91746, Officers: Min-Wu (Winnie) Yen, Secretary (Qualifying Individual), Chun (Bryan) Fang, Director/President, Application Type: New NVO License.

Optima Cargo & Logistics Inc (NVO & OFF), 9550 NW 12th Street, #16B, Miami, FL 33172, Officers: Juan C. Nunez, President/COO (Qualifying Individual), Alcira D. Tablada, Vice President, Application Type: QI Change.

OTX Logistics, Inc. (NVO & OFF), 90 SW 3rd Street, Unit 3604, Miami, FL 33130, Officers: Harald Oechsner, President/Director (Qualifying Individual), Spencer Chun C. Lam, Director, Application Type: New NVO & OFF License.

Prolog Services Inc. dba PSI Ocean Freight Systems (NVO & OFF), 5803 Sovereign Drive, #220, Houston, TX 77036, Officers: Stanley A. Egbo, President/Secretary (Qualifying Individual), Ernest C. Agu, Vice President, Application Type: Add NVO Service.

Rapidex USA LLC (NVO & OFF), 71 Veronica Avenue, Suite 2, Somerset, NJ 08873, Officers: Mohamed Y. Ali, Manager (Qualifying Individual), Abdul S. Mohamed, Member, Application Type: Add OFF Service.

Reece Ventures, LLC dba I love Moving (NVO & OFF), 8939 S. Sepulveda Blvd., #102, Los Angeles, CA 90045, Officers: Alexander Ravich, General Manager-Officer (Qualifying Individual), Franka Reece, Member/Manager, Application Type: New NVO & OFF License.

Rescigno Logistics Group, LLC (NVO & OFF), 1 Windsor Cove, Suite 301, Columbia, SC 29223, Officers: Michael D. Rescigno, Member (Qualifying Individual), Sigrid M. Rescigno, Member, Application Type: New NVO & OFF License.

Rhino Moving Inc (NVO), 1130 S. Powerline Road, #103, Deerfield Beach, FL 33442, Officers: Yoel Kegnovich, President/Treasurer (Qualifying Individual), Michelle Kegnovich, Vice President/Secretary, Application Type: New NVO License.

Sealand Freight LLC (NVO), 3925 Galveston Road, #A, Houston, TX 77017, Officers: Walid M. Hattab, Chief Executive Member (Qualifying Individual), Ola M. Ghunmat, Member, Application Type: New NVO License.

Straight Forwarding, Inc. (NVO), 20974 Currier Road, City of Industry, CA 91789, Officer: Yi-Hsiang (Eric) Wu, President/Secretary/Treasurer/CFO (Qualifying Individual), Application Type: New NVO License.

Superior Freight Services, Inc. (NVO & OFF), 1230 Trapp Road, Eagan, MN 55121, Officers: David L. Stark, President/Director (Qualifying Individual), Brian O'Donnell, Vice President/Director, Application Type: Add OFF Service.

Trade Logistics Corp. (NVO & OFF), 3954 Osprey Ct., Weston, FL 33331, Officer: Jaime Garces, President/Vice President/Secretary/Treasurer (Qualifying Individual), Application Type: New NVO & OFF License.

Transmark Logistics, Inc. dba Transmark Logistics (OFF), 22217 68th Avenue South, Kent, WA 98032, Officers: Rosemary Weber, Vice President (Qualifying Individual), Murvin P. Allen, President/Secretary/Treasurer, Application Type: New OFF License.

Tri-Crown Shipping LLC (NVO & OFF), 3545 West River Commons, Douglasville, GA 30135, Officer: Abimbola Badejo, Member (Qualifying Individual), Application Type: New NVO & OFF License.

We International Inc. (NVO & OFF), 6690 Amador Plaza Road, Suite 115, Dublin, CA 94568, Officers: Leanne Kwan, Vice President (Qualifying Individual), Fangbin Wu, President, Application Type: QI Change.

World Logistics LLC (NVO & OFF), 12130 Dixie, #B, Redford, MI 48239, Officer: Samar Hazime, President/Member (Qualifying Individual), Application Type: New NVO & OFF License.

Dated: March 2, 2012.

Karen V. Gregory,

Secretary.

[FR Doc. 2012–5563 Filed 3–6–12; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR Part 515.

License no.	Name/Address	Date reissued
020479F	Karon Jones dba Keen Machinery and Export,425 Sandy Lane, Dublin, TX 76446.	February 11, 2012.
021869F	Merco Air & Ocean Cargo, Inc., 6 Fir Way, Cooper City, FL 33026	February 1, 2012.
022258F	Platinum Moving Services, Inc. 7610–P Rickenbacker Drive, Gaithersburg, MD 20879.	January 04, 2012.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2012–5558 Filed 3–6–12; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License Number: 021014N.

Name: Magic Transport, Inc.

Address: Pepsi Industrial Park, PR–2, KM 19.5, Interior BO Candelaria, Toa Baja, PR 00949.

Order Published: FR: 3/1/12 (Volume 77, No. 41, Pg. 12584).

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2012–5560 Filed 3–6–12; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocation

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary license has been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515, effective on the corresponding date shown below:

License Number: 020852N.

Name: OTS Int'l, Inc. dba OTS Logistics.

Address: 3120 Via Mondo, Rancho Dominguez, CA 90220.

Date Revoked: January 27, 2012.

Reason: Voluntarily surrendered license.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2012–5562 Filed 3–6–12; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0388]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

Proposed Project: Let's Move! Cities, Towns, and Counties—OMB No. 0990–0388—Extension—Office of the Assistant Secretary for Planning and Evaluation (ASPE).

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting an extension from the Office of Management and Budget (OMB) to conduct a survey of public sector organizations for the *Let's Move!* Cities, Towns and Counties Initiative. *Let's Move!* is a comprehensive initiative, launched by the First Lady, dedicated to solving the challenge of childhood obesity within a generation. Combining comprehensive strategies with common sense, *Let's Move!* is about:

- Putting children on the path to a healthy future during their earliest months and years;
- Giving parents helpful information and fostering environments that support healthy choices;
- Providing healthier foods in our schools;
- Ensuring that every family has access to healthy, affordable food; and
- Helping kids become more physically active.

Let's Move! Cities, Towns, and Counties emphasizes the unique ability of communities to solve the challenge locally, and the critical leadership mayors and elected officials can provide to bring communities together and spur action. The initiative is designed to encourage mayors and elected officials to adopt a long-term, sustainable and holistic approach to fighting childhood obesity.

This activity is requesting comment on the burden for a baseline survey for local or county officials who have chosen to participate in *Let's Move!* Cities, Towns, and Counties. The survey requests information about the activities the locality is choosing to undertake. The responses to these questions will be used to show progress and successes over time for localities participating in *Let's Move!* Cities, Towns, and Counties. Separate notices will be published for subsequent surveys.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Government Official (city, town, county)	Baseline Survey.	1,000	1	15/60	250

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2012–5541 Filed 3–6–12; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ).

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Friday, April 13, 2012, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, (301) 427–1456. For press-related information, please contact Alison Hunt at (301) 427–1244.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827–4840, no later than Friday, March 16, 2012. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850. Ms. Campbell's phone number is (301) 427–1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships.

The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Friday, April 13, 2012, there will be a subcommittee meeting for the National Healthcare Quality and Disparities Report scheduled to begin at 7:30 a.m. The Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The AHRQ Director will present her update on current research, programs, and initiatives. The final agenda will be available on the AHRQ Web site at *www.ahrq.gov* no later than Friday, April 6, 2012.

Dated: February 15, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–5436 Filed 3–6–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the Research Centers in Primary Care Practice Based Research and Learning (P30) applications are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: Research Centers in Primary Care Practice Based Research and Learning (P30).

Date: March 29, 2012 (Open on March 29 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: February 27, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–5434 Filed 3–6–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–12–12BT]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC at (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Community Transformation Grants: Use of System Dynamic Modeling and Economic Analysis in Select Communities—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of a multi-component evaluation plan for the Community Transformation Grant program (CTG), CDC is seeking OMB approval to collect the information needed to conduct cost and cost-benefit analyses relating to the implementation of CTG-funded community interventions. Using a system dynamics approach, CDC also plans to conduct simulation modeling which will integrate the cost data with other data to predict selected chronic disease outcomes and their associated monetary impacts under various scenarios. CDC and NIH have previously collaborated on the development of analytic tools for system dynamics modeling under more limited conditions. The collection and analysis of actual cost data from CTG awardees will support the expansion and refinement of these analytic tools with respect to short-, intermediate- and long-term outcomes for large-scale, community-based programs that employ multiple policy and environmental change strategies.

Information to be collected from participating CTG awardees includes the interventions to be implemented; expenditures for labor, personnel, consultants, materials, travel, services, and administration; in-kind contributions; and partner organizations and their expenditures. Information will be collected electronically via a user-friendly, Web-based CTG Cost Study Instrument (CTG–CSI). Respondents will be a subset of 30 out of 35 CTG awardees funded specifically for implementation activities. CDC will select awardees for participation in the cost data collection based on a list of priority interventions appropriate for cost analysis.

Results of this data collection and planned analyses, including improvements in CDC's analytic and modeling tools, will be used to assist CTG awardees, CDC, and HHS in choosing intervention approaches for particular populations that are both beneficial to public health and cost-effective.

OMB approval is requested for the first three years of a five-year project. CDC requests OMB approval by June 1, 2012, to initiate data collection on July 1, 2012. CDC plans to seek an extension of OMB approval to support information collection through the end of the five-year award period.

Information will be collected electronically on a quarterly schedule. The estimated burden per response is 13 hours and there are no costs to respondents except their time to participate in the survey. The total estimated annualized burden hours are 1,560.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
CTG Awardee	CTG–CSI	30	4	13

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012–5495 Filed 3–6–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–12–12EX]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 and send comments to Kimberly S. Lane, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Formative Research for the Development of CDC's Act Against AIDS Social Marketing Campaigns Targeting Consumers—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

More than 1 million people are estimated to be living with Human Immunodeficiency Virus (HIV) in the United States. Estimates of HIV incidence released by the CDC indicate that 56,300 people became infected with HIV in 2006. HIV disproportionately affects men, particularly men who have sex with men (MSM) and African-American men. HIV is also a real threat to other communities at high risk such as the Hispanic/Latino community.

In response to the continued HIV epidemic in our country, CDC launched *Act Against AIDS (AAA)* in 2009, a 5-year, multifaceted communication campaign consisting of several campaigns targeting various high-risk populations. The overall goals of AAA are to increase HIV/AIDS awareness and reduce HIV incidence in the United States. Each AAA campaign uses mass media and direct-to-consumer channels to deliver HIV prevention, awareness, and testing messages. Some campaigns are designed to provide basic education and increase awareness of HIV/AIDS among the general public, and others are targeted to specific subgroups or communities at greatest risk for HIV infection, including MSM, African Americans, HIV-positive individuals and other minority populations.

As part of the overarching *AAA* campaign, CDC requests OMB approval to collect information from consumer groups over a three-year period. This study will encompass four rounds of data collection utilizing interviews, focus groups, and brief surveys. The

results from this data collections will be used to develop AAA's social marketing campaigns designed to increase HIV/AIDS awareness and knowledge, understand HIV prevention behaviors, improve HIV testing rates, challenge commonly held misperceptions about HIV, and promote HIV prevention and risk reduction among consumers. The research results will be used to develop materials for six specific HIV social marketing campaigns under the umbrella of the larger *Act Against AIDS* campaign. The campaigns will target consumers aged 18–64. Some campaigns will target the general public as a whole and other campaigns will focus on specific subpopulations at greatest risk for HIV infection. The target audiences will include Latinos, men who have sex with men (MSM), HIV-positive individuals and African Americans. These data will assist CDC in addressing the HIV prevention needs of specific campaign audiences and make appropriate funding decisions regarding campaign development or campaign direction.

Respondents will be members of the targeted consumer groups aged 18–64 recruited from areas with high HIV/AIDS prevalence and incidence such as New York, NY; Los Angeles, CA; Washington, DC; Chicago, IL; Atlanta, GA; Miami, FL; Philadelphia, PA; Houston, TX; San Francisco, CA; Baltimore, MD; Dallas, TX or other cities as appropriate. Respondents for this data collection will participate in a focus group, in-depth interview, or intercept interview. Focus group and in-depth interview respondents will be recruited by professional recruiting firms. The professional recruiting firms will utilize a proprietary database of individuals who have agreed to be contacted for potential participation in various studies. Project staff will recruit intercept interview respondents in venues where the general public tend to gather, such as health fairs or other community events.

Information collection will begin after receiving approval and end three years from approval. The study will screen 1,538 people per year for eligibility. Of the 1,538 people screened, it is expected that 500 people will participate in focus groups, 500 people will participate in in-depth interviews. All focus group and in-depth interview participants will complete a brief paper and pencil survey. Seven hundred people will participate in intercept interviews. The total estimated burden for this one-time data collection is 6,852 hours. Annualizing this information over 3 years results in an estimated annualized burden of 2,284 hours.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Individuals (males and females) aged 18–64	Study screener	1,538	1	2/60	51
Individuals (males and females) aged 18–64	In-Depth Interview Guide.	500	1	60/60	500
Individuals (males and females) aged 18–64	Focus Group Guide	500	1	120/60	1,000
Individuals (males and females) aged 18–64	Paper and Pencil Survey.	1,000	1	30/60	500
Individuals (males and females) aged 18–64	Intercept Interview Guide.	700	1	20/60	233
Total					2,284

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–5494 Filed 3–6–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: 45 CFR Part 1305 Head Start Eligibility Verification.

OMB No.: 0970–0374.

Description: The requirements for establishing proof of eligibility for the enrollment of children in Head Start programs are documented in 45 CFR 1305.4(e). Each child's record must include a signed document by an employee identifying those documents which were reviewed to determine eligibility. Presently there is no uniform document which the employee must sign. This form will be used to facilitate an efficient and accurate determination of children's eligibility for Head Start enrollment.

Respondents: Head Start grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Eligibility Verification	1,600	750	0.08	96,000

Estimated Total Annual Burden Hours: 96,000.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comments on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All Requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–5501 Filed 3–6–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Appeal Procedures for Head Start Grantees and Current or Prospective Delegate Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Adverse Action	20	1	26	520

Estimated Total Annual Burden Hours: 520.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

OMB No.: 0980–0242.

Description: Section 646 of the Head Start Act requires the Secretary to prescribe a timeline for conducting administrative hearings when adverse actions are taken or proposed against Head Start or Early Head Start grantees or delegate agencies. The Office of Head Start is proposing to renew without changes this rule which implements these requirements and which prescribe when a grantee must submit information and what that information should include to support a contention that adverse action should not be taken.

Respondents: Head Start and Early Head Start grantees and delegate agencies against which the Head Start Bureau has taken or proposes to take adverse actions.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 2012–5499 Filed 3–6–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: Head Start Facilities Construction, Purchase and Major Renovations.

OMB No.: 0970–0193.

Description: The Head Start Bureau is proposing to renew, without changes, the information collections activities for the regulations in 45 CFR part 1309. The part contains the administrative requirements applicable to Head Start and Early Head Start grantees, when applying for funding to purchase, renovate or construct Head Start program facilities. The regulations ensure that standard business practices are applied when acquiring real property and that federal interest is preserved in properties acquired with public funds. The regulations further ensure compliance with all other federal statues applicable to the expenditure of federal funds when acquiring real property.

Respondents: Head Start and Early Head Start programs are delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per respondent	Total burden hours
Administrative Requirements	200	1	41	8,200

Estimated Total Annual Burden Hours: 8,200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comments on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All Requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 2012–5421 Filed 3–6–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 8, 2012, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AAC@fda.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss supplemental biologics license application 125249, ARCALYST (rilonacept) injection, Regeneron Pharmaceuticals, Inc., for the following proposed indication: ''ARCALYST (rilonacept) is an interleukin-1 blocker indicated for the prevention of gout flares during initiation of uric-acid lowering therapy in adult patients with gout. ARCALYST has not been studied for longer than 16 weeks in this clinical setting.''

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 24, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 16, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 17, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 2, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–5487 Filed 3–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–N–0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on April 3, 2012, from 8 a.m. to 5 p.m. and on April 4, 2012, from 8 a.m. to 3:30 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is: 301 589–5200.

Contact Person: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 3, 2012, during the morning session, the committee will discuss the development of an animal model of pneumonic plague (plague infection with extensive lung involvement) in African Green Monkeys and provide advice concerning the relevance of the animal model to pneumonic plague in humans resulting from exposure to *Yersinia pestis* (the bacteria that causes plague) in a bioterrorism event.

During the afternoon session, the committee will discuss the data provided to support the safety and efficacy of ciprofloxacin for the treatment of pneumonic plague in humans. The National Institute of Allergy and Infectious Diseases (NIAID) has submitted efficacy data for ciprofloxacin, based on treatment in an animal model of plague. Safety and other supportive information is derived from clinical studies and post-marketing experience in humans.

On April 4, 2012, the committee will discuss the data provided to support the safety and efficacy of levofloxacin for the treatment of pneumonic plague in humans. Johnson and Johnson Pharmaceutical Research and Development, LLC (on behalf of Janssen Pharmaceuticals, Inc.), has submitted efficacy supplements for LEVAQUIN (levofloxacin) tablets, injection, and oral solution (NDA 20–634, NDA 20–635, and NDA 21–721, respectively) for treatment of pneumonic plague. Efficacy data for levofloxacin is based on treatment in an animal model of plague. Safety and other supportive information is derived from clinical studies and post-marketing experience in humans.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 19, 2012. Oral presentations from the public will be scheduled between approximately 10 a.m. to 10:30 a.m. and 2:30 p.m. to 3 p.m. on April 3, 2012, and between approximately 11 a.m. to 11:30 a.m. on April 4, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 19, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 1, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–5455 Filed 3–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 77 FR 7594–7595 dated February 13, 2012).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Maternal and Child Health Bureau (RM): (1) Establish the Office of Policy Coordination (RM10); (2) establish the Office of Epidemiology and Research (RM9); (3) within the Office of Epidemiology and Research, establish the Division of Research (RM91) and the Division of Epidemiology (RM92); (4) rename the Division of Research, Training and Education (RM4) to the Division of Maternal and Child Health Workforce Development (RM4); and (5) transfer the research function from the newly named Division of Maternal and Child Health Workforce Development (RM4) to the newly established Office of Epidemiology and Research (RM9).

Chapter RM—Maternal and Child Health Bureau

Section RM–10, Organization

Delete in its entirety and replace with the following:

The Maternal and Child Health Bureau (RM) is headed by the Associate Administrator, Maternal and Child Health Bureau (MCHB), who reports directly to the Administrator, Health Resources and Services Administration. MCHB includes the following components:

(1) Office of the Associate Administrator (RM);

(2) Office of Operations and Management (RM1);

(3) Division of Services for Children with Special Health Needs (RM2);

(4) Division of Child, Adolescent and Family Health (RM3);

(5) Division of Maternal and Child Health Workforce Development (RM4);

(6) Division of Healthy Start and Perinatal Services (RM5);

(7) Division of State and Community Health (RM6);

(8) Division of Home Visiting and Early Childhood Systems (RM8);

(9) Office of Epidemiology and Research (RM9); and

(10) Office of Policy Coordination (RM10).

Section RM–20, Functions

(1) Delete the functional statement for the Maternal and Child Health Bureau (RM) and replace in its entirety.

Office of the Associate Administrator (RM)

The Office of the Associate Administrator (OAA) provides national leadership and policy direction for Maternal and Child Health Bureau (MCHB) programs. These programs are designed to improve the health of women of childbearing age, infants, children, adolescents and their families, children with special health needs, and persons with hemophilia. Specifically, OAA: (1) Coordinates the planning, development, implementation, and evaluation of the programs and activities of the Bureau; (2) facilitates effective, collaborative relationships with other health and related programs; (3) establishes a program mission, goals, objectives, and policy with broad Administration guidelines; (4) serves as the focal point for managing the Bureau-wide strategic planning operation as it relates to long and short range programmatic goals and objectives for the Bureau; (5) arranges and provides technical assistance to assure that the grantees meet program expectations; (6) serves as principal contact point to HRSA, the Department, Office of Management and Budget (OMB), and the White House on matters concerning the health status of America's mothers and children; and (7) provides information and reports on the Bureau's programs to public, health, education and related professional associations, Congress, other Federal agencies, OMB, and the White House.

Office of Operations and Management (RM1)

The Office of Operations and Management (OOM) plans, directs, coordinates, and evaluates Bureau-wide administrative and management activities; coordinates and monitors program and administrative policy implementation, and maintains close liaison with officials of HRSA and the Office of the Secretary on matters relating to these activities. Specifically, OOM: (1) Serves as the Associate Administrator's and Bureau's principal source for management and administrative advice and assistance; (2) provides or serves as liaison for program support services; (3) provides leadership on intergovernmental activities of the Bureau which requires administrative direction or intergovernmental activities of the Bureau, requiring central direction of cross-cutting administrative issues affecting program activities; (4) participates in the development of strategic plans, regulatory activities, policy papers, and legislative proposals relating to MCH programs; (5) plans, coordinates and facilitates the Bureau's Agency agreement activities; (6) coordinates human resource activities for the Bureau; (7) provides guidance to the Bureau on financial management activities; (8) determines State allocations of MCH Block Grant funds based on formula and current census data; (9) provides organization and management analysis, develops policies and procedures for internal operation, and interprets and implements the Administration's management policies, procedures and systems; (10) coordinates the Bureau's program and administrative delegations of authority activities; (11) provides staff services in operation planning and program analysis; (12) is responsible for paperwork management functions, including the development and maintenance of Bureau manual issuances; (13) provides direction regarding new developments in office management activities; and (14) coordinates Bureau funds and resources for grants, contracts and cooperative agreements.

Division of Services for Children with Special Health Needs (RM2)

The Division of Services for Children with Special Health Needs (DSCSHN) provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease among children with special health care needs (CSHCN) and their families, with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such populations. Specifically, DSCSHN carries out the following activities: (1) Administers a program that supports the development of systems of care and services for CSHCN and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for CSHCN and their families; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other MCHB Divisions and Offices in

promoting program objectives and the mission of the Bureau; (5) provides consultation and technical assistance to State programs for CSHCN and to local communities, consistent with a Bureau-wide technical assistance consultation plan and in concert with other agencies and organizations; (6) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for CSHCN and their families; (7) develops and implements a national program for those at risk or living with genetic diseases, including a national program for persons with hemophilia, implementing a system of demonstration projects related to early identification, referral, treatment, education, and counseling information; (8) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act, Supplemental Security Income, Individuals with Disabilities Education Act, and others) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for CSHCN, including those with genetic disorders, and their families; (9) promotes the dissemination of information on preventive health services and advances in the care and treatment of CSHCN, including those with genetic disorders, and their families; (10) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for CSHCN, including those with genetic disorders, and their families; (11) participates in the development of interagency agreements concerning Federal assignees to State MCHB programs; (12) carries out a national program on traumatic brain injury; and (13) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Child, Adolescent and Family Health (RM3)

The Division of Child, Adolescent and Family Health provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease and injury among children, adolescents, young adults and their families with special emphasis on the development and implementation of family-centered, comprehensive, coordinated, community-based and culturally competent systems of care for such populations. Specifically, the Division: (1) Administers a program which supports the development of systems of care and services for children, adolescents, young adults and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for children, adolescents, young adults and their families; (3) accounts for the administration of funds and other resources for grants, contracts, and programmatic consultation and assistance; (4) coordinates with MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) serves as the focal point within the Bureau in implementing programmatic statutory requirements for State programs for children, adolescents, young adults and their families; (6) provides consultation and technical assistance to State programs for children, adolescents, young adults and their families and to local communities, consistent with a Bureau-wide technical assistance consultation plan, working with other agencies and organizations; (7) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for children, adolescents, young adults and their families; (8) carries out a national program supporting Child Death Review systems; (9) carries out a national program on school health activities; (10) carries out a national program designed to improve the provision of emergency medical services for children; (11) carries out a national program designed to improve the provision of oral health services for children; (12) carries out a national program on injury prevention for children and adolescents; (13) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for children, adolescents, young adults and their families; (14) disseminates information on preventive health services and advances in the care and treatment of children, adolescents, young adults and their families; (15) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children, adolescents, young adults and their families; and (16) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Maternal and Child Health Workforce Development (RM4)

The Division of Maternal and Child Health Workforce Development provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs related to professional and public education activities and training, focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families, with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such populations. Specifically, the Division carries out the following activities: (1) Administers a program which supports the development of systems of care and services for children and their families; (2) develops policies and guidelines and promulgates standards through professional and public education and training activities for the Bureau; (3) plans, implements, and administers a program of professional education and training designed to improve the promotion of health and prevention of disease among infants, children, adolescents, and children with special health needs; (4) provides grants to institutions of higher learning, provides support for the education and training of health professionals designed to promote health and prevent disease among infants, children, adolescents, and children with special health care needs; (5) develops, coordinates and implements systematic technical assistance and consultation on professional training strategies to State and local agencies and organizations or groups concerned with the promotion of health and prevention of disease among infants, children, adolescents, and children with special health care needs; (6) provides support, through grants and contracts, for community demonstration projects (e.g. Healthy Tomorrows Partnership for Children Projects) that support the development of family-centered, community-based initiatives that foster collaboration among community organizations, individuals, agencies, businesses, health professionals and families; (7) accounts for the administration of funds and other resources for grants, contracts, cooperative agreements and programmatic consultation and assistance; (8) coordinates with other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (9) provides liaison with public, private, professional

and voluntary organizations on programs and activities; and (10) disseminates information on professional and public education and training activities to States and localities.

Division of Healthy Start and Perinatal Services (RM5)

The Division of Healthy Start and Perinatal Services provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on maternal, infant, family, and women's health to improve and strengthen the awareness of, access, delivery, quality, coordination and evidence-based services for targeted populations, especially for the vulnerable and those at high-risk for poor health and health outcomes. The Division strives to eliminate health disparities and provide high quality continuous health care, including health promotion and disease prevention, throughout the lifespan of women and their families from infancy to preconception, prenatal, postpartum, and inter-conception through support of local, State, and national innovative, evidenced-based projects of health promotion and risk reduction. Specifically, the Division is responsible for the following activities: (1) Administers local, State, and national programs on perinatal and women's health with an emphasis on infant mortality reduction and eliminating disparities in perinatal infant, maternal and women's health outcomes; (2) provides policy direction, technical assistance, national resource development and dissemination; professional consultation and development to address national trends in maternal, infant, family, and women's health status and gaps in the evidence-based healthcare services for these populations as well as Division programs; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with Bureau, Agency, departmental, and intra-departmental initiatives in promoting Division's programs objectives and the mission of the Bureau; (5) serves as the focal point within the Agency, and frequently the Department on programmatic infant, maternal, and women's health initiatives; (6) coordinates the Advisory Committee on Infant Mortality; (7) provides liaison with public, private, professional and non-governmental organizations for Division programs; (8) disseminates information on Division programs to the local, State, and national audiences; (9) participates in the development of strategic plans, health services research and evaluation, regulatory activities, policy papers, legislative proposals, and fiscal strategic planning, administration, and analysis relating to Division programs; (10) provides leadership, technical assistance and professional consultation to Central and Regional Office staff of the Bureau, Agency, Department, other Federal agencies, students and allied groups to improve services; and (11) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of State and Community Health (RM6)

In collaboration with MCHB Divisions and Offices, the Division of State and Community Health (DSCH) serves as the organizational focus for the administration of responsibilities related to the Maternal and Child Health (MCH) Block Grant to States Program. Specifically, DSCH: (1) Works in partnership with States, primarily through the Title V Block Grant, communities, and grantees to assure continued improvement in the health, safety and well-being of the MCH population; (2) provides national leadership, direction, coordination, and administrative oversight related to the development and management of the State MCH Block Grant applications and the annual reports; (3) based on independent and high quality evaluations and reviews, which includes the tracking of State progress in meeting performance objectives, develops, plans, manages, and monitors a Bureau-wide program of technical assistance and consultation in collaboration with other Bureau Divisions and related health programs; (4) develops and manages an online information system to facilitate in the collection, analysis and dissemination of national and State performance, program and financial State Title V information and data to various constituencies including the public, States, and Congress about the Block Grant to States Program; (5) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services in the Block Grant to States Program; (6) develops, plans, manages, and monitors the State Systems Development Initiative (SSDI) grant to the States' program; (7) develops, plans, manages and monitors contracts, grants, and cooperative agreements, including the Partnership for State Title V MCH Leadership Community, Partnership for Urban MCH Leadership Community, and State Public Health Coordinating Center for Autism Cooperative Agreements; (8) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals and budget submissions relating to health services for women of childbearing age, infants, children, adolescents, children with special health care needs and their families; and (9) develops guidance and reporting forms for the State Title V MCH Block Grant Applications/Annual Reports and Five-Year Needs Assessments and other discretionary grants and cooperative agreements.

Division of Home Visiting and Early Childhood Systems (RM8)

The Division of Home Visiting and Early Childhood Systems plans, develops, implements, directs, monitors, and evaluates national programs to promote, improve, and maintain the health and development of young children (through 8 years of life) and their families. Specifically, the Division conducts the following activities: (1) Serves as a national focus for leadership in and coordination of Federal, regional, State, local, and non-governmental efforts to define the health and development issues of young children and their relationship to the family to identify problems and opportunities and assist in the development of programs that address such problems and promote opportunities to enhance wellness; (2) develops, interprets, and/or disseminates policies, regulations, standards, guidelines, new knowledge and program information for the various programs and relevant services; (3) establishes and maintains cooperative relationships within this Agency, with other Federal agencies, and with other relevant public and private organizations to extend and improve health, safety, research, educational and training programs focused on young children and their families; (4) carries out, in collaboration with the Administration for Children and Families, a national maternal, infant and early childhood home visiting program; (5) administers and manages a program of grants and contracts that will enhance services to improve and promote the health and safety of young children and their families; (6) coordinates within this Agency and with other Federal programs to extend and improve comprehensive coordinated services and promote integrated state-based systems of care for this population; and (7) provides technical assistance and professional consultation to field and

headquarters staff, to State and local health personnel, to other Federal agencies, and to voluntary and professional organizations on all aspects of health and safety and provision of appropriate care for this population.

Office of Epidemiology and Research (RM9)

The Office of Epidemiology and Research provides leadership in the following two areas: (1) Identifies and analyzes data needs and utilizes and implements a data strategy and program focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families with special emphasis on the development and implementation of family centered, comprehensive, coordinated care, community-based and culturally competent systems of care for such populations, and (2) plans, directs, coordinates, and monitors national maternal and child health research programs.

The Office has oversight responsibility and coordinates the work of the Division of Research, and the Division of Epidemiology. Specifically the Office: (1) Provides a central location for all MCH Data and Research; (2) administers funds and other resources for grants, contracts, and cooperative agreements; (3) provides MCHB leadership in assisting in the development of the National Survey on Child Health and the National Survey on Children with Special Health Needs; (4) coordinates the Health Information Technology efforts of the Bureau; and (5) disseminates information on data collection and analysis on women of childbearing age, infants, children and children with special health care needs.

Division of Research (RM91)

The Division of Research provides national leadership in identifying, analyzing, and responding to the need for the development of new knowledge through research projects of regional and national significance relating to the promotion of health and prevention of disease among infants, children, adolescents, women, children with special health care needs, and their families. Specifically, the Division conducts the following activities: (1) Plans, implements, and administers a program of research activities designed to improve the promotion of health and prevention of disease among the MCH population; (2) develops, coordinates and implements systematic technical assistance and consultation on research to State and local agencies and organizations or groups concerned with the promotion of health and prevention of disease among the MCH population; (3) supports research studies related to the promotion of health and prevention of disease among the MCH population; and (4) provides through grants and contracts, support for applied research projects and research networks designed to advance the knowledge for the promotion of health and prevention of disease among the MCH population.

Division of Epidemiology (RM92)

The Division of Epidemiology provides national leadership in identifying and analyzing data need and develops and implements a data strategy and program focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families with special emphasis on the development and implementation of family centered, comprehensive, coordinated care, community-based and culturally competent systems of care for such populations. Specifically, the Division carries out the following functions: (1) Builds data capacity at the national, state, and local levels through grants, cooperative agreements and contracts, and supports a broad range of data collection, analyses and projects designed to improve the health status of infants, children, adolescents, and CSHCN; (2) develops and coordinates a series of programs to strengthen the present and future capacity in MCH epidemiology; (3) plans, implements and monitors a system of placement of Federal employees assigned to State health agencies; (4) coordinates and monitors the placement of Centers for Disease Control and Prevention sponsored epidemiologists in State agencies; and (5) provides for data program coordination at all levels of Bureau program operations through analyses of program data, trends and other issues concerning scientific and policy matters, the provision of health services and data and information related to the promotion of health and prevention of disease among infants, children, adolescents, and CSHCN.

Office of Policy Coordination (RM10)

The Office of Policy Coordination serves as the Bureau focal point for the management of the planning, evaluation, legislation, and legislative implementation activities, including the development, coordination, and dissemination of program objectives, policy positions, reports and strategic plans. Specifically, the Office develops, coordinates, and maintains a data and information system designed to improve implementation of Title V and other Bureau programs and develops, coordinates, and implements systematic technical assistance and consultation on data and information systems and evaluation approaches to State and local agencies and organizations or groups concerned with infants, children, adolescents, and CSHCN. In addition, the Office carries out the following program development functions: (1) Advises and assists the Associate Administrator for Maternal and Child Health and other Bureau staff in the development, coordination and management of strategic planning and policy documents, responses to departmental and HRSA initiatives, and information papers to support Bureau and Administration goals; (2) interprets evaluation requirements and develops, coordinates, and manages the preparation of the annual evaluation plans and activities, and conducts or contracts for specific evaluation projects related to the performance of MCHB programs; (3) develops, coordinates, and manages Bureau activities related to the development, clearance, and dissemination of **Federal Register** notices, guidelines, Federal Opportunity Notices, final grant reports, and periodic and annual reports to other Federal and non-Federal agencies; (4) participates in the development of the Annual Online Performance Appendix and assures the Bureau fulfills the Department of Health and Human Services' performance planning and reporting requirements; (5) coordinates activities closely and continuously with the HRSA Office of Planning, Analysis and Evaluation and the MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (6) provides liaison with public, private, professional, and voluntary organizations on programs related to MCHB planning and legislative issues; and (7) performs the Executive Secretariat function for the Bureau, controlling correspondence and clearing policy documents as appropriate.

Section RM–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: February 24, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012–5447 Filed 3–6–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Customs Modernization Act Recordkeeping Requirements

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Customs Modernization Act Recordkeeping Requirements. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before May 7, 2012, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Customs Modernization Act Recordkeeping Requirements.

OMB Number: 1651–0076.

Form Number: None.

Abstract: The North American Free Trade Agreement Implementation Act, Title VI, known as the Customs Modernization Act (Mod Act) amended title 19 U.S.C. 1508, 1509 and 1510 by revising Customs and Border Protection (CBP) laws related to recordkeeping, examination of books and witnesses, regulatory audit procedures and judicial enforcement. Specifically, the Mod Act expanded the list of parties subject to CBP recordkeeping requirements, distinguished between records which pertain to the entry of merchandise and financial records needed to substantiate the correctness of information contained in entry documentation, and identified a list of records which must be maintained and produced upon request by CBP. The information and records are used by CBP to verify the accuracy of the claims made on the entry documents regarding the tariff status of imported merchandise, admissibility, classification/nomenclature, value and rate of duty applicable to the entered goods. The Mod Act record keeping requirements are provided for by 19 CFR part 163.

Action: CBP proposes to extend the expiration date of this information collection with a change to the burden hours as a result of a revised estimate of the number of respondents currently complying with these recordkeeping provisions.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 5,459.

Estimated Number of Total Annual Responses: 5,459.

Estimated Time per Response: 1,040 hours.

Estimated Annual Burden Hours: 5,677,360.

Dated: March 1, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2012–5458 Filed 3–6–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: General Declaration

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60–Day Notice and request for comments; Extension of an existing collection of information.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the General Declaration (CBP Form 7507). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before May 7, 2012, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and

Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: General Declaration (Outward/Inward).

OMB Number: 1651–0002.

Form Number: CBP Forms 7507.

Abstract: CBP Form 7507, *General Declaration (Outward/Inward),* must be filed for all aircraft entering under the provisions of 19 CFR 122.41. This form is used to document clearance by the arriving aircraft at the required inspectional facilities and inspections by appropriate regulatory agency staffs. CBP Form 7507 collects information about the flight routing, the numbers of passengers embarking and disembarking, a declaration of health for the persons on board, details about disinfecting and sanitizing treatments during the flight, and a declaration attesting to the accuracy and completeness and truthfulness of all other documents that make up the manifest.

CBP Form 7507 is authorized by 19 U.S.C. 1431, 1433, and 1644a; 39 U.S.C. 602(b) and provided for by 19 CFR 122.43, 122.48, 122.54, 122.73, and 122.

Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Forms 7507.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 500.

Estimated Number of Total Annual Responses: 1,000,000.

Estimated Time per Response: 5 minutes.

Dated: March 1, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2012–5459 Filed 3–6–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30–Day Notice and request for comments; Extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (76 FR 75893) on December 5, 2011, allowing for a 60-day comment period. One comment was received. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before April 6, 2012.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR).

OMB Number: 1651–0125.

Form Number: None.

Abstract: On August 5, 2004, the United States entered into the Dominican Republic-Central America-United States Free Trade Agreement with Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua, (also known as CAFTA–DR.) The Agreement was approved by Congress in section 101(a) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act, Public Law 109–53, 119 Stat. 462 (19 U.S.C. 4001 et seq.), as amended by Sec. 1634(d) of the Pension Protection Act of 2006 (Pub. L. 109–280), and provides for preferential tariff treatment of certain goods originating in one or more of the CAFTA–DR countries. It was signed into law on August 2, 2005, and the president proclaimed the implementation dates as follows: El Salvador (3/1/06), Honduras (4/1/06), Nicaragua (4/1/04), Guatemala (7/1/06), Dominican Republic (3/1/07) and Costa Rica (1/1/09).

In order to ascertain if CAFTA–DR imported goods are eligible for preferential tariff treatment, a certification and supporting documents may be requested by CBP. This collection of information is provided for by 19 CFR 10.583 through 19 CFR 10.592. Guidance on filing claims under CAFTA–DR may be found at: *http://www.cbp.gov/xp/cgov/trade/trade_programs/international_agreements/free_trade/dominican_republic/.*

Current Actions: CBP proposes to extend the expiration date of this information collection with a change to the burden hours. Specifically, estimated number of responses was lowered from 10,000 to 3,000 based on revised estimates by CBP. The time per response was increased from 24 minutes to 2 hours based on public comments that CBP received. There is no change to the information collected.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 1,000.

Estimated Number of Responses per Respondent: 3.

Estimated Number of Total Annual Responses: 3,000.

Estimated Time per Response: 2 hours.

Estimated Total Annual Burden Hours: 6,000.

Dated: March 1, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2012–5460 Filed 3–6–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5610–N–04]

Notice of Proposed Information for Public Comment for: Public Housing Capital Fund Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Each year Congress appropriates funds to approximately 3,100 Public Housing Authorities (PHAs) for modernization, development, financing, and management improvements. The funds are allocated based on a complex formula. The forms in this collection are used to appropriately disburse and utilize the funds provided to PHAs. Additionally, these forms provide the information necessary to approve a financing transaction in addition to any Capital Fund Financing transactions. Respondents include the approximately 3,100 PHA receiving Capital Funds and any other PHAs wishing to pursue financing.

DATES: *Comments Due Date:* May 7, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed information collection. Comments should refer to the proposal by name and/or OMB Control Number (2577–0157) and should be sent to: Colette Pollard, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4176, Washington, DC 20410; telephone: 202–402–2400, (this is not a toll-free number) or email Ms. Pollard at *Colette.Pollard@hud.gov*. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339. (Other than the HUD USER information line and TTY numbers, telephone numbers are not toll-free.) Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Public Housing Capital Fund Program.

OMB Control Number, if applicable: 2577–0157.

Description of the need for the information and proposed use: HUD is revising the Actual Modernization Cost Certificate (AMCC)—HUD Form 53001 contained within the Public Housing Capital Fund Program collection OMB Control Number 2577–0157. The AMCC reports on actual cost of modernization activities upon its completion. The grant type title on the AMCC of Comprehensive Improvement Assistance Program and Comprehensive Grant Program will be changed to Capital Fund Program (CFP). The PHA certification section will have two check mark boxes added for the PHA to certify if the Single Audit Act (SAA) A–133 requirement applies to the CFP grant specified on the AMCC (1-check box for SAA requirement applicable, 1-check box for SAA requirement not applicable). The ''HUD Use Only section'' will remove ''the audited costs agree with the costs shown above'' due to numerous PHAs that are not subject to Independent Public Accountant (IPA) audit requirements.

Agency form numbers, if applicable: HUD Form 53001—Actual Modernization Cost Certificate.

Members of Affected Public: State, Local or Local Government and Non-profit organization.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of respondents is 3,100 with 72,844 annual responses and the total reporting burden is 265,267 hours.

Status of the proposed information collection: Revision of an existing collection.

Authority: section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 1, 2012.

Merrie Nichols-Dixon,

Deputy Director for Office of Policy, Program and Legislative Initiatives.

[FR Doc. 2012–5506 Filed 3–6–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5603–N–17]

Notice of Submission of Proposed Information Collection to OMB; Housing Choice Voucher Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Public housing agencies (PHA) apply for funding to assist very low-income families to lease or purchase housing. PHAs maintain records on participant eligibility, unit acceptability, lease and housing assistance payments, and budget and payment documentation. In some cases, PHAs voluntarily divest their voucher programs to a receiving PHA. PHAs may also project-base a portion of their vouchers or use their vouchers under the Homeownership Option.

DATES: *Comments Due Date:* April 6, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577–0169) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov.* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Housing Choice Voucher Program.

OMB Approval Number: 2577–0169.

Form Numbers: HUD 52681, HUD 52515, HUD 52517, HUD 52531A, HUD 52531B, HUD 52580, HUD 52580–A, HUD 52641, HUD 52641–A, HUD 52642, HUD 52665, HUD 52667, HUD 52672, HUD 52642–A, HUD 5253A, HUD 52649, HUD 52646, 52578B, HUD 52530–B, HUD 52530C, 52530–B, HUD 52681–b, HUD 52530–A, HUD–52663, 52681B.

Description of the Need for the Information and Its Proposed Use:

Public housing agencies (PHA) apply for funding to assist very low-income families to lease or purchase housing. PHAs maintain records on participant eligibility, unit acceptability, lease and housing assistance payments, and budget and payment documentation. In some cases, PHAs voluntarily divest their voucher programs to a receiving PHA. PHAs may also project-base a portion of their vouchers or use their vouchers under the Homeownership Option.

Frequency of Submission: On occasion.

	Number of respondents	Annual responses	×	Hours per response	Burden hours
Reporting Burden	492,450	0.00617		0.407	1,239,192

Total Estimated Burden Hours: 1,239,192.

Status: Revision of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: February 29, 2012.

Colette Pollard,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2012–5557 Filed 3–6–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14200000–BJ0000]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on April 6, 2012.

DATES: Protests of the survey must be filed before April 6, 2012 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Blaise Lodermeier, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5128 or (406) 896–5009, *bloderme@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Bureau of Land Management, Butte Field Office, and was necessary to determine federal interest lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 14 N., R. 3 W.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines and a portion of Tract 38, and the survey of Tract 38B, and supplemental plat showing the new area for Tract 38A, Township 14 North, Range 3 West, Principal Meridian, Montana, was accepted February 28, 2012.

We will place a copy of the plat, in one sheet, in the open files. It will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in one sheet, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in one sheet, until the day after we

have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Steve L. Toth,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2012–5498 Filed 3–6–12; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14200000–BJ0000]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on April 6, 2012.

DATES: Protests of the survey must be filed before April 6, 2012 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Marvin Montoya, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5124 or (406) 896–5009, *Marvin_Montoya@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the United State Forest Service, Region 1, Bozeman, Montana, and was necessary to determine federal interest lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 9 S., R. 8 E.

The plat, in one sheet, representing the dependent resurvey of portions of the north boundary of Yellowstone National Park, the east boundary, the subdivisional lines, and Mineral Survey No. 43, Placer, the subdivision of section 24, and the metes and bounds survey of Lot 10, section 24, Township 9 South, Range 8 East, Principal Meridian, Montana, was accepted February 28, 2012.

We will place a copy of the plat, in one sheet, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in one sheet, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in one sheet, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Steve L. Toth,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2012–5496 Filed 3–6–12; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZ956000.L14200000.BJ0000.241A]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey; Arizona.

SUMMARY: The plats of survey of the described lands were officially filed in the Arizona State Office, Bureau of Land Management, Phoenix, Arizona, on dates indicated.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat representing the survey of the south and north boundaries, the subdivisional lines and the subdivision of certain sections, Township 35 North, Range 24 East, accepted February 27, 2012, and officially filed February 29, 2012, for Group 1079, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs, Navajo Regional Office.

A person or party who wishes to protest against any of these surveys must file a written protest with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004–4427. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Stephen K. Hansen,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2012–5484 Filed 3–6–12; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC 00900.L16100000.DP0000]

Notice of Public Meeting, Eastern Montana Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Eastern Montana Resource Advisory Council (RAC) will meet as indicated below.

DATES: The next regular meeting of the Eastern Montana RAC will be held on April 4, 2012, in Billings, Montana. The meeting will start at 8 a.m. and adjourn at approximately 3:30 p.m.

ADDRESSES: When determined, the meeting location will be announced in a news release.

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Public Affairs Specialist, BLM Eastern Montana/Dakotas District, 111 Garryowen Road, Miles City, Montana 59301, (406) 233–2831, *mark_jacobsen@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–677–8339 to contact the above individual during normal business

hours. The FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member council advises the Secretary of the Interior through the BLM on a variety of planning and management issues associated with public land management in Montana. At these meetings, topics will include: Miles City and Billings Field Office manager updates, subcommittee briefings, work sessions and other issues that the council may raise. All meetings are open to the public and the public may present written comments to the council. Each formal RAC meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations should contact the BLM as provided above.

Dated: February 28, 2012.

M. Elaine Raper,

Eastern Montana—Dakotas District Manager.

[FR Doc. 2012–5492 Filed 3–6–12; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Intent To Repatriate Cultural Items: U.S. Fish and Wildlife Service, Office of Law Enforcement, Lakewood, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service, Office of Law Enforcement, in consultation with the appropriate Indian tribe, has determined that the cultural items listed below meet the definition of sacred objects and repatriation to the Indian tribe stated below may occur if no additional claimants come forward. Representatives of any Indian tribe that believes itself to be culturally affiliated with the cultural items may contact the U.S. Fish and Wildlife Service, Office of Law Enforcement.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the cultural items should contact the U.S. Fish and Wildlife Service, Office of Law Enforcement, at the address below by April 6, 2012.

ADDRESSES: Special Agent in Charge, U.S. Fish and Wildlife Service, Office of Law Enforcement, 134 Union Blvd., Room 550, Lakewood, CO 80228, telephone (303) 236–7540.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate two cultural items in the possession of the U.S. Fish and Wildlife Service, Office of Law Enforcement, that meet the definition of sacred objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the U.S. Fish and Wildlife Service, Office of Law Enforcement. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

These items came into the possession and control of the U.S. Fish and Wildlife Service (USFWS), Office of Law Enforcement, pursuant to a criminal investigation. The items were forfeited to the U.S. Government by the U.S. Customs Service in separate forfeiture actions in January, February and March 2001, and the Federal criminal investigations are now complete.

USFWS contracted with expert consultants to review the collection and consulted with 11 tribes having interest or affiliation in the objects. Three tribes filed claims requesting repatriation of objects from the collection. Upon review, the USFWS determined that two sacred objects (Item 6: Crow lumpwood dance wand and Item 46: spithorn headdress) are subject to repatriation to the Crow Tribe of Montana.

Determinations Made by the U.S. Fish and Wildlife Service, Office of Law Enforcement

Based on the above-mentioned information, officials of the USFWS have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), two of the cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between two cultural objects and the Crow Tribe of Montana.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these sacred objects should contact the Special Agent in Charge, U.S. Fish and Wildlife Service, Office of Law Enforcement, 134 Union Blvd., Room 550, Lakewood, CO 80228; telephone (303) 236–7540, April 6, 2012. Repatriation of the sacred objects the Crow Tribe of Montana may proceed after that date if no additional claimants come forward.

The U.S. Fish and Wildlife Service, Office of Law Enforcement, Lakewood, CO, is responsible for notifying the Crow Tribe of Montana that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5584 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Intent To Repatriate Cultural Items: Maxey Museum, Whitman College, Walla Walla, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Maxey Museum, in consultation with the appropriate Indian tribes, has determined that the cultural items meet the definition of unassociated funerary objects and repatriation to the Indian tribes stated below may occur if no additional claimants come forward. Representatives of any Indian tribe that believes itself to be culturally affiliated with these cultural items may contact Maxey Museum.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the cultural items should contact Maxey Museum at the address below by April 6, 2012.

ADDRESSES: Gary Rollefson, Maxey Museum, Whitman College, 345 Boyer Avenue, Walla Walla, WA 99362, telephone (509) 527–4938.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of Maxey

Museum that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

The following cultural items in Maxey Museum came from various collectors and sites within the Columbia River Plateau near the confluence of the Columbia and Snake rivers in Oregon and Washington. The unassociated funerary objects are: 25 stone implements; 3 pestle fragments; 2 pounding stones; 1 grooved weight; 1 grooved stone; 1 mortar; 2 pestles; 1 bone awl; and 1 lot of metal beads.

The stone implements were collected at various points along the Columbia and Snake Rivers, most notably by H.T. Harding and Dr. H.S. Brode. Journals and donor records indicate these objects were collected in the following locations: ''opposite the mouth of the Yakima River'' in September 1925 and May 1928; ''along the Columbia River, north of Pasco, Washington. Presented by H.S. Brode, April 14, 1929''; and along the ''Snake River, N.E. Burbank, Washington. H.S. Brode and J.C. Bunnell, 1930.'' The bone awl was purchased by Whitman College from Mr. Clarence McBeth on January 24, 1930, and is listed as being from ''an Indian grave along the Snake River in Walla Walla County, southwest of Riparia, Washington.'' Lastly, the metal beads were taken from ''an Indian grave, Tucannon Burial Ground'' and were donated to Maxey Museum by F.G. Moor in 1944.

A detailed assessment of the cultural items was made by Maxey Museum professional staff in consultation with representatives of the Confederated Tribes and Bands of the Yakama Nation, Washington; Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Reservation, Oregon; Confederated Tribes of the Warm Springs Reservation of Oregon; Nez Perce Tribe, Idaho (previously listed as Nez Perce Tribe of Idaho) (hereafter referred to as ''The Tribes''); and the Wanapum Band, a non-Federally recognized Indian group (hereafter referred to as ''The Indian Group''). The Tribes and The Indian Group claim these objects as unassociated funerary objects due to the provenance indicating the objects were removed from known burial sites within the Columbia River Plateau. All of the collection sites are located in close proximity to one another within the traditional territories of The Tribes and The Indian Group.

The collection site opposite the mouth of the Yakima River is a burial area now known as site 45FR101, Chiawana Park. Lewis and Clark mentioned how heavily this area was populated during the fall salmon runs. Fishing stations, processing areas and villages were located on both sides of the Columbia River and at the mouth of the Yakima River (Moulton 1988) and north of Pasco, WA. A large excavation of this site occurred in 1967 by the Mid-Columbia Archaeology Society under the direction of Dr. David Rice. Approximately, sixteen burials were removed to a repository at Washington State University; however, some of the remains were reported to be repatriated to the Yakama Nation in 1982 (Collins et al. 2001, LaSarge 2002). Brode and Bunnell collected together in the 1930s at NE Burbank, WA, on the Snake River. Hood Park is northeast of Burbank and was heavily used as a traditional salmon fishing and processing area by The Tribes and The Indian Group (Iverson 1976; Croghan 1999; Wright 2001). Wright (2001:6) states that burials were located and removed from the day use and campground areas of the park in the mid-1970s. Erosion along the Snake River shoreline has also caused burials to be exposed from this location over the years. The Tucannon Burial Ground is congruent with Smithsonian site 45CO1, a large, heavily looted fishing station, open camp and burial site at the mouth of the Tucannon River where it joins the Snake River. The Indian grave described as southwest of Riparia, WA, is likely in the vicinity of the mouth of the Tucannon River. The Tucannon River is situated along a traditional cultural boundary between the Nez Perce Tribe and the Confederated Tribes of the Umatilla Reservation.

Based on traditional lifeways, past and present, The Tribes and The Indian Group are direct descendant communities of the native people that jointly used the lower Snake and Columbia rivers. As aboriginal lifeways were being extinguished by Euro-American settlement of the Pacific Northwest, treaties were negotiated and signed with the native communities during the expansion of Washington and Oregon territories. The native peoples in these territories were removed from the shores of the Columbia and Snake rivers to the Colville, Umatilla, Warm Springs, Yakama and Nez Perce reservations. The Wanapum Band was removed from the rivers as well but was not put on a reservation of their own. Cultural affiliation is further reinforced by living, enrolled members of The Tribes and The Indian Group that have documented ancestors buried along the lower Snake and Columbia rivers.

Determinations Made by Maxey Museum

Officials of Maxey Museum have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 37 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from specific burial sites of Native American individuals.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and The Tribes and The Indian Group.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact Gary Rollefson, Maxey Museum, Whitman College, 345 Boyer Avenue, Walla Walla, WA 99362, telephone (509) 527–4938, before April 6, 2012. Repatriation of the unassociated funerary objects to The Tribes and The Indian Group may proceed after that date if no additional claimants come forward.

Maxey Museum is responsible for notifying The Tribes and The Indian Group that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5581 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

[2253–665]

National Park Service

Notice of Intent To Repatriate Cultural Items: U.S. Fish and Wildlife Service, Office of Law Enforcement, Lakewood, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service, Office of Law Enforcement, in consultation with the appropriate Indian tribes, has determined that the cultural items listed below meet the definition of sacred objects and/or objects of cultural patrimony and repatriation to the Indian tribes stated below may occur if no additional claimants come forward. Representatives of any Indian tribe that believes itself to be culturally affiliated with the cultural items may contact the U.S. Fish and Wildlife Service, Office of Law Enforcement.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the cultural items should contact the U.S. Fish and Wildlife Service, Office of Law Enforcement, at the address below by April 6, 2012.

ADDRESSES: Special Agent in Charge, U.S. Fish and Wildlife Service, Office of Law Enforcement, 134 Union Blvd., Room 550, Lakewood, CO 80228, telephone (303) 236–7540.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate eight cultural items in the possession of the U.S. Fish and Wildlife Service, Office of Law Enforcement, that meet the definition of sacred objects and/or objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the U.S. Fish and Wildlife Service, Office of Law Enforcement. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

These items came into the possession and control of the U.S. Fish and Wildlife Service (USFWS), Office of Law Enforcement, pursuant to a criminal investigation. The items were forfeited to the U.S. Government by the U.S. Customs Service in separate forfeiture actions in January, February and March 2001. These items were transferred to the USFWS on August 21, 2001, and the Federal criminal investigations are now complete.

USFWS contracted with expert consultants to review the collection and consulted with 11 tribes having interest or affiliation in the objects. Three tribes filed claims requesting repatriation of objects from the collection. Upon review, the USFWS determined that three objects of cultural patrimony and five sacred objects are subject to repatriation to the Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana. The five sacred objects include Items 42 and 43: two rattles, Item 26: Imosna, deer dew claws (Bandoleer), and Items 5 and 70: two splithorn headdresses, one with a trailer. The three objects of cultural patrimony include Item 11: notched warrior's dance whip or wand, Item 18: Napeshi spear or dance spear, and Item 41: notched warrior's dance whip or quirt. Items 5 and 70 (splithorn headdresses) are both sacred objects and objects of cultural patrimony.

Determinations Made by the U.S. Fish and Wildlife Service, Office of Law Enforcement

Based on the above-mentioned information, officials of the USFWS have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), three of the cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(3)(D), three of the cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(3)(C) and 25 U.S.C. 3001(3)(D), two of the cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents, and have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between eight cultural objects and the Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these sacred objects and/or objects of cultural patrimony should contact the Special Agent in Charge, U.S. Fish and Wildlife Service, Office of Law Enforcement, 134 Union Blvd., Room 550, Lakewood, CO 80228, telephone (303) 236–7540, April 6, 2012. Repatriation of the sacred objects and/or objects of cultural patrimony to the Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana may proceed after that date if no additional claimants come forward.

The U.S. Fish and Wildlife Service, Office of Law Enforcement, Lakewood, CO, is responsible for notifying the Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5570 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Intent To Repatriate Cultural Items: U.S. Fish and Wildlife Service, Office of Law Enforcement, Lakewood, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service, Office of Law Enforcement, in consultation with the appropriate Indian tribe, has determined that the cultural items listed below meet the definition of sacred objects and object of cultural patrimony and repatriation to the Indian tribe stated below may occur if no additional claimants come forward. Representatives of any Indian tribe that believes itself to be culturally affiliated with the cultural items may contact the U.S. Fish and Wildlife Service, Office of Law Enforcement.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the cultural items should contact the U.S. Fish and Wildlife Service, Office of Law Enforcement, at the address below by April 6, 2012.

ADDRESSES: Special Agent in Charge, U.S. Fish and Wildlife Service, Office of Law Enforcement, 134 Union Blvd., Room 550, Lakewood, CO 80228, telephone (303) 236–7540.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate 27 cultural items in the possession of the U.S. Fish and Wildlife Service, Office of Law Enforcement, that meet the definition of sacred objects and object of

cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the U.S. Fish and Wildlife Service, Office of Law Enforcement. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

These items came into the possession and control of the U.S. Fish and Wildlife Service (USFWS), Office of Law Enforcement, pursuant to a criminal investigation. Items 1–60 were forfeited to the U.S. Government by the U.S. Customs Service in separate forfeiture actions in January, February and March 2001. These items were transferred to the USFWS on August 21, 2001. Items 61–69 were abandoned to the USFWS on November 15, 2001. All objects listed below were either seized or abandoned from various private collectors or a public museum pursuant to Federal criminal investigations, which are now complete.

USFWS contracted with expert consultants to review the collection and consulted with 11 tribes having interest or affiliation in the objects. Three tribes filed claims requesting repatriation of objects from the collection. Upon review, the USFWS determined that 27 of the objects are subject to repatriation to the Blackfeet Tribe of the Blackfeet Indian Reservation of Montana. The 27 sacred objects are Item 1: All Brave-Dog society rattle; Item 2: bird bone whistle; Item 3: man's straight-up headdress; Item 4: man's headdress; Items 7 and 12: eagle bone whistle; Item 15: dance club; Item 16: dance staff; Items 23–25: replica Natoas sundance headdress; Item 27: eagle tail feathers; Item 34: medicine pipe owner's headband and hair feathers; Item 35: replica of the Little Dog Thunder medicine pipe; Item 36: replica of the secondary pipe from a medicine pipe bundle; Item 37: eagle feather headdress; Item 38: rawhide cylindrical case with replica bear knife medicine bundle; Items 44 and 47: war bonnet; Item 48: straight-up bonnet; Items 49 and 53: Brave Dog Society rattles; Item 55: weasel tail shirt; Item 56: buckskin leggings; Item 64: eagle feather headdress; Item 65: medicine bundle; and Item 69: leather tipi bag and contents. Item 16 (dance staff) is both a sacred object and an object of cultural patrimony.

Determinations Made by the U.S. Fish and Wildlife Service, Office of Law Enforcement

Based on the above-mentioned information, officials of the USFWS have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), 26 of the cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(3)(C) and 25 U.S.C. 3001(3)(D), one of the cultural items described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents, and has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the 27 cultural objects and the Blackfeet Tribe of the Blackfeet Indian Reservation of Montana.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these sacred objects and object of cultural patrimony should contact the Special Agent in Charge, U.S. Fish and Wildlife Service, Office of Law Enforcement, 134 Union Blvd., Room 550, Lakewood, CO 80228; telephone (303) 236–7540, April 6, 2012. Repatriation of the sacred objects and object of cultural patrimony to the Blackfeet Tribe of the Blackfeet Indian Reservation, Montana may proceed after that date if no additional claimants come forward.

The U.S. Fish and Wildlife Service, Office of Law Enforcement, Lakewood, CO, is responsible for notifying the Blackfeet Tribe of the Blackfeet Indian Reservation, Montana that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5578 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: USDA Forest Service, Daniel Boone National Forest, Winchester, KY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture, Forest Service, Daniel Boone National Forest, has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is no cultural affiliation between the remains and any present-day Indian tribe. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains may contact the Daniel Boone National Forest, Winchester, KY. Repatriation of the human remains to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact the Forest Tribal Liaison, Daniel Boone National Forest, at the address below by April 6, 2012.

ADDRESSES: Forest Tribal Liaison, Daniel Boone National Forest, Winchester, KY 40391, telephone (859) 745–3138.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the Daniel Boone National Forest, Winchester, KY. The human remains and associated funerary objects were removed from three counties, Estill, McCreary, and Morgan, inside the Daniel Boone National Forest, KY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by professional staff

of the U.S. Department of Agriculture, Forest Service, Daniel Boone National Forest, in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Cherokee Nation, Oklahoma; Eastern Band of Cherokee Indians of North Carolina; Eastern Shawnee Tribe of Oklahoma; Shawnee Tribe, Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

History and Description of the Remains

In March 1988, human remains representing, at minimum, one individual were removed from site 15MCY414 in McCreary County, KY. The human remains from this site were collected from disturbed contexts by Forest Service archeologists. No known individual was identified. The human remains include 22 fragments representing one adult female and are from an unknown context within the site. Artifacts recovered from the site indicate that this site was occupied during the Late Woodland cultural period dating from A.D. 500 to 1000. The five associated funerary objects are 1 deer bone, 1 turkey bone, 1 battered stone, 1 triangular projectile point, and 1 fragment of shell tempered pottery.

On October 18, 1985, human remains representing, at minimum, one individual were removed from site 15MO103 in Morgan County, KY. The human remains from this site were turned over to the Daniel Boone National Forest by the physical anthropologist at Eastern Kentucky University when it was determined they were acquired illegally from the Daniel Boone National Forest. No known individual was identified. The nearly complete human remains of one individual are from an unknown context within the site. Artifacts recovered from the site indicate that this site was occupied during the Late Archaic cultural period dating from 3000 to 1000 B.C. The two associated funerary objects are 1 McWhinney projectile point and 1 freshwater mussel shell.

In 1983, human remains representing, at minimum, one individual were removed from site 15MCY76 in McCreary County, KY. The human remains from this site were collected during site recordation by Forest Service archeologists. No known individual was identified. The fragment of a human femur is from an unknown context within the site. Artifacts recovered from the site indicate that this site was occupied during the Prehistoric cultural period dating prior to A.D. 1700. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown location in Estill County, KY. The human remains were found in an artifact collection stored at the Daniel Boone National Forest while doing a collections inventory. No known individual was identified. The fragmentary human remains are from an unknown context within the site. Artifacts recovered from the site indicate that this site was occupied during the prehistoric cultural period dating prior to A.D. 1700. No associated funerary objects are present.

Determinations Made by the Daniel Boone National Forest

Officials of the Daniel Boone National Forest have determined that:

- Based on the approximate date of artifacts recovered from the site, these human remains are Native American.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian tribe.
- Other credible lines of evidence indicate that the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Absentee-Shawnee Tribe of Indians of Oklahoma; Cherokee Nation, Oklahoma; Eastern Band of Cherokee Indians of North Carolina; Eastern Shawnee Tribe of Oklahoma; Shawnee Tribe, Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the seven associated funerary objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 43 CFR 10.11(c)(2)(i), the disposition of the human remains and associated funerary objects will be to the Absentee-Shawnee Tribe of Indians of Oklahoma; the Cherokee Nation, Oklahoma; Eastern Band of Cherokee Indians of North Carolina; Eastern Shawnee Tribe of Oklahoma; Shawnee Tribe, Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains or any other Indian tribe that believes it satisfies the criteria in 43 CFR 10.11(c)(2)(i) should contact the Forest Tribal Liaison, Daniel Boone National Forest, Winchester, KY 40391, telephone (859) 745–3138, before April 6, 2012. Disposition of the human remains to the Absentee-Shawnee Tribe of Indians of Oklahoma; the Cherokee Nation, Oklahoma; Eastern Band of Cherokee Indians of North Carolina; Eastern Shawnee Tribe of Oklahoma; Shawnee Tribe, Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma may proceed after that date if no additional claimants or requestors come forward.

The Daniel Boone National Forest is responsible for notifying the Absentee-Shawnee Tribe of Indians of Oklahoma; the Cherokee Nation, Oklahoma; Eastern Band of Cherokee Indians of North Carolina; Eastern Shawnee Tribe of Oklahoma; Shawnee Tribe, Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5583 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: Maxey Museum, Whitman College, Walla Walla, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Maxey Museum has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact Maxey Museum. Repatriation of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary objects should contact Maxey Museum at the address below by April 6, 2012.

ADDRESSES: Gary Rollefson, Maxey Museum, Whitman College, 345 Boyer Avenue, Walla Walla, WA 99362, telephone (509) 527–4938.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of Maxey Museum. The human remains and associated funerary objects were removed from the general vicinity of the Snake River and Columbia River in the Columbia River Plateau, in the counties of Walla Walla, Benton, Franklin, and Columbia, WA, and Umatilla, OR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Maxey Museum professional staff in consultation with representatives of the Confederated Tribes and Bands of the Yakama Nation, Washington; Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Reservation, Oregon; Confederated Tribes of the Warm Springs Reservation of Oregon; Nez Perce Tribe, Idaho (previously listed as Nez Perce Tribe of Idaho) (hereafter referred to as ''The Tribes''); and the Wanapum Band, a non-Federally recognized Indian group (hereafter referred to as ''The Indian Group'').

History and Description of the Remains

In the early to middle 20th century, human remains representing, at minimum, six individuals were removed from an unknown location near the confluence of the Columbia River and Snake River in the counties of Walla Walla, Benton, Franklin, and Columbia, WA, and Umatilla, OR. The four burials contained the remains of five adults and one child. No known individuals were identified. The accession also contains 26 associated funerary objects, consisting of: 3 envelopes with writing; 1 lot of small pieces of leather belt or harness; 1 lot of charcoal pieces; 3 metal bells; 1 pipe stem; 1 piece of iron; 1 envelope with no writing; 1 chert flake; 1 lot of animal teeth; 1 partially burnt fragment of wood; 1 corroded (non-human) fragment, substance and use unknown; 1 copper ring; 1 copper bell; 3 metal wheel gears; 1 lot of metal rings from a pipe stem; 1 lot of glass beads strung on cotton; 1 large animal tooth; and 3 copper bracelets.

In 1998, the human remains and associated funerary objects listed above were discovered in a large box in a storage closet in Memorial Hall, the main administrative building of Whitman College, and subsequently moved to Maxey Museum at Whitman College. Since the time of Maxey Museum's acquisition, the human remains and associated funerary objects were not removed from the box or intermingled with other collections, nor were the objects displayed. Envelopes found in the box read: ''Robert Grant, Field Representative, Whitman College, Walla Walla.'' Many of the associated funerary objects are personal items, and others are objects typical to cremation burials. All of the objects are typical funerary objects found on the Columbia River Plateau.

Although minimal provenance information exists for these objects, Whitman College was involved with many excavations along the Columbia River from Plymouth, WA, to Richland, WA, and along the Snake River in the first half of the 20th century, as well as receiving donated remains and funerary objects from inadvertent discoveries in the area. Through consultation with The Tribes and The Indian Group and an assessment of the objects as representative funerary objects commonly found in Columbia River Plateau burials, it is asserted that this collection of associated funerary objects belongs to the human remains in the box.

Based on traditional lifeways, past and present, The Tribes and The Indian Group are direct descendant communities of the native people that jointly used the lower Snake and Columbia rivers. As aboriginal lifeways were being extinguished by Euro-American settlement of the Pacific Northwest, treaties were negotiated and signed with the native communities during the expansion of Washington and Oregon territories. The native peoples in these territories were removed from the shores of the Columbia and Snake rivers to the Colville, Umatilla, Warm Springs, Yakama and Nez Perce reservations. The Wanapum Band was removed from the rivers as well but was not put on a reservation of their own. Cultural affiliation is further reinforced by living, enrolled members of The Tribes and The Indian Group that have documented ancestors buried along the lower Snake and Columbia rivers.

Determinations Made by Maxey Museum

Officials of Maxey Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of six individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 26 associated funerary objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects to The Tribes and The Indian Group.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Gary Rollefson, Maxey Museum, Whitman College, Walla Walla, WA 99362, telephone (509) 527–4938, before April 6, 2012. Repatriation of the human remains and associated funerary objects to The Tribes and The Indian Group may proceed after that date if no additional claimants come forward.

Maxey Museum is responsible for notifying The Tribes and The Indian Group that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5577 Filed 3–6–12; 8:45 am]

BILLING CODE 4310–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: History Colorado, Denver, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: History Colorado (formerly the Colorado Historical Society) has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is insufficient evidence to reasonably establish cultural affiliation

between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact History Colorado. Disposition of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact History Colorado at the address below by April 6, 2012.

ADDRESSES: Sheila Goff, NAGPRA Liaison, History Colorado, 1200 Broadway, Denver, CO 80203, telephone (303) 866–4531.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of History Colorado, Denver, CO. The human remains were recovered from various locations in Colorado, including Huerfano and Pueblo Counties.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

In 2010 and 2011, a detailed assessment of the human remains was made by History Colorado professional staff with representatives of the Arapahoe Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma (formerly the Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Crow Tribe of Montana; Fort Sill Apache Tribe of Oklahoma; Jicarilla Apache Nation, New Mexico; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Ohkay Owingeh, New Mexico (formerly the Pueblo of San Juan); Pawnee Nation of Oklahoma; Pueblo of Cochiti, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Santa Clara, New Mexico; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Shoshone Tribe of the Wind River Reservation, Wyoming; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; and the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah. The following tribes were invited to consult but did not participate: Kiowa Indian Tribe of Oklahoma; Oglala Sioux Tribe of the Pine Ridge Reservation; Pueblo of Santa Ana, New Mexico; Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho; Standing Rock Sioux Tribe of North & South Dakota; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma; and the Zuni Tribe of the Zuni Reservation, New Mexico.

In 2000, the following tribes previously consulted on Office of Archaeology and Historic Preservation (OAHP) Case Number 98: Kiowa Indian Tribe of Oklahoma; Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota; and the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota. In addition, the following tribes consulted on OAHP Case Number 175 in 2010: Hopi Tribe of Arizona; Navajo Nation, Arizona, New Mexico, & Utah; Pueblo of Acoma, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Tesuque, New Mexico; Ysleta Del Sur Pueblo, Texas; and the Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of the Remains

In July 1994, human remains representing, at minimum, one individual were removed from private property, site 5HR117, in Huerfano County, CO, by citizens who turned the remains over to the county coroner. The coroner notified the State Archaeologist, who authorized an on-site investigation and collected additional remains. All remains were subsequently transferred to History Colorado, where they are identified as OAHP Case Number 98. No known individuals were identified. The 17 non-diagnostic associated funerary objects are 16 whole and partial disk shell beads and one deer scapula.

The remains had been disturbed; therefore, the original burial context is unknown. A stone enclosure typical of Apishapa sites is located about 50m north of where the remains were recovered but it is not possible to establish a relationship between the structure and the remains. Osteological analysis determined that the individual is of Native American ancestry.

In May 1997, human remains representing, at minimum, one individual were transferred to History Colorado by the Denver Medical Examiner's Office. They are identified as OAHP Case Number 128. There is no information available as to where or how the remains were recovered.

The medical examiner determined that the individual is of Native American ancestry. He observed that some molars had been intentionally removed and that there was minor deterioration of the bone, suggesting an estimated antiquity of 40 to 150 years.

In 1955, human remains representing, at minimum, three individuals were removed from a cave in Pueblo County, CO, by private citizens. The cave is located on private land. At some time after discovery, they were transferred to Southern Colorado State College. In 1999, when the college closed the Laboratory of Anthropology, the remains were transferred to History Colorado. They are identified as OAHP Case Number 175. No known individuals were identified. The eight non-diagnostic associated funerary objects are one leather bag in fragments; one lock of black hair; one lot of corn cobs; one strand of braided grass; one modified animal bone, possibly a bone bead blank; one lot of cordage fragments; one faunal bone and one animal tooth.

Osteological analysis determined the individuals are of Native American ancestry. One individual exhibits cranial modification.

In 1981, human remains representing, at minimum, one individual were removed from 5PE6811 in Pueblo County, CO, by a private citizen. The site is located on private land. In July 2008, he turned the remains over to the county coroner. The State Archaeologist was notified as they were determined to be Native American. The location of removal was investigated and the remains transferred to History Colorado. They are identified as OAHP Case Number 263. No known individuals were identified. The 11 non-diagnostic associated funerary objects are beads manufactured between 1790 and the late 1800s.

Osteological analysis determined that the individual was of Native American ancestry.

Determinations Made by History Colorado

Officials at History Colorado have determined that:

- Pursuant to 25 U.S.C. 3001(9)–(10), the human remains described above represent the physical remains of six

individuals of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(3)(A), the 36 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains described above and any present-day Indian tribe.

History Colorado has determined that the human remains are ''culturally unidentifiable'' under NAGPRA, 43 CFR 10.9(e)(6). In 2006, History Colorado, in partnership with the Colorado Commission of Indian Affairs, Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah conducted consultations with the tribes that have ancestral ties to the state of Colorado to develop the process for disposition of culturally unidentifiable Native American human remains and associated funerary objects originating from inadvertent discoveries on Colorado state and private lands. As a result of the consultation, a process was developed, *Process for Consultation, Transfer, and Reburial of Culturally Unidentifiable Native American Human Remains and Associated Funerary Objects Originating From Inadvertent Discoveries on Colorado State and Private Lands* (2008) (unpublished, on file with the Colorado Office of Archaeology and Historic Preservation). The remains described above were recovered in or transferred from state agencies in the Great Plains Consultation Region, as established by the *Process,* and tribes consulted are those who have expressed their wishes to be notified of discoveries in this region.

The Native American Graves Protection and Repatriation Review Committee (Review Committee) is responsible for recommending specific actions for disposition of culturally unidentifiable human remains. On November 3–4, 2006, the *Process* was presented to the Review Committee for consideration. A January 8, 2007 letter on behalf of the Review Committee from the Designated Federal Officer transmitted the provisional authorization to proceed with the *Process* upon receipt of formal responses from the Jicarilla Apache Nation, New Mexico, and Kiowa Indian Tribe of Oklahoma, and subject to forthcoming conditions imposed by the Secretary of the Interior. On May 15–16, 2008, the responses from the Jicarilla Apache Nation, New Mexico, and Kiowa Indian Tribe of Oklahoma were submitted to the Review Committee. On September 23, 2008, the Assistant Secretary for Fish and Wildlife and Parks, as the designee for the Secretary of the Interior, transmitted the authorization for the disposition of culturally unidentifiable human remains according to the *Process* and NAGPRA, pending publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

43 CFR 10.11 was promulgated March 15, 2010, providing a process for the disposition of culturally unidentifiable Native American human remains recovered from tribal or aboriginal lands as established by the final judgment of the Indian Claims Commission or U.S. Court of Claims, a treaty, Act of Congress, or Executive Order, or other authoritative governmental sources. There is no available evidence indicating that the human remains reported in this notice originated from tribal or aboriginal lands, thus making them eligible for disposition under the *Process.*

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Sheila Goff, NAGPRA Liaison, History Colorado, 1200 Broadway, Denver, CO 80203, telephone (303) 866–4531, before April 6, 2012. Transfer of control of the human remains to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah may proceed after that date if no additional claimants come forward.

History Colorado is responsible for notifying the Apache Tribe of Oklahoma; Arapahoe Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma; Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Comanche Nation, Oklahoma; Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Crow Tribe of Montana; Fort Sill Apache Tribe of Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Kewa Pueblo, New Mexico (formerly Pueblo of Santo Domingo); Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota; Ohkay Owingeh, New Mexico (formerly the Pueblo of San Juan); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes) (formerly Paiute Indian Tribe of Utah (Cedar City Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes)); Pawnee Nation of Oklahoma; Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; San Juan Southern Paiute Tribe of Arizona; Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho; Shoshone Tribe of the Wind River Reservation, Wyoming; Southern Ute Indian Tribe of the Southern Ute Indian Reservation, Colorado; Standing Rock Sioux Tribe of North & South Dakota; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah; Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakoni), Oklahoma; Ysleta Del Sur Pueblo of Texas; and the Zuni Tribe of the Zuni Reservation, New Mexico, that this notice has been published.

Dated: March 2, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5586 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2253–665]

Notice of Inventory Completion: History Colorado, Denver, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: History Colorado (formerly the Colorado Historical Society) has

completed an inventory of human remains, in consultation with the appropriate Indian tribes, and has determined that there is insufficient evidence to reasonably establish cultural affiliation between the human remains and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains may contact History Colorado. Disposition of the human remains to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact History Colorado at the address below by April 6, 2012.

ADDRESSES: Sheila Goff, NAGPRA Liaison, History Colorado, 1200 Broadway, Denver, CO 80203, telephone (303) 866–4531.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of History Colorado, Denver, CO. The human remains were recovered from Rio Blanco and Routt Counties, CO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

In 2010 and 2011, a detailed assessment of the human remains was made by History Colorado professional staff in consultation with representatives of the Jicarilla Apache Nation, New Mexico; Ohkay Owingeh, New Mexico (formerly the Pueblo of San Juan); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes) (formerly Paiute Indian Tribe of Utah (Cedar City Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes)); Pueblo of Cochiti, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Santa Clara, New Mexico; Shoshone Tribe of the Wind River Reservation, Wyoming; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; and the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah. The following Tribes were invited to consult but did not participate: Kiowa Indian Tribe of Oklahoma; Pueblo of Santa Ana, New Mexico; Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho; and the Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of Remains

In the 1930s, human remains representing, at minimum, one individual were removed from Routt County, CO, on or near the Sullivan Ranch by a private citizen. They are identified as Office of Archaeology and Historic Preservation (OAHP) Case Number 271. In March 2009, after the citizen passed away, the remains were turned over to the Department of Archaeology and Historic Preservation of the state of Washington by his descendants, requesting that they be returned to the land they originated from in Colorado. The remains were transferred to History Colorado in March 2010 for disposition under NAGPRA. No known individuals were identified. No associated funerary objects are present.

The citizen was employed as a sheepherder on the Sullivan Ranch at the time he removed the remains. He later moved to Washington, taking the remains with him. The Washington State Physical Anthropologist determined that the remains were of Native American ancestry.

In November 2007, human remains representing, at minimum, one individual were discovered in a recently purchased home in Rio Blanco County, CO, by a private citizen. She notified the county sheriff, who collected the remains. They were transferred to History Colorado in June 2010. The remains are identified as OAHP Case Number 273. No known individuals were identified. No associated funerary objects are present.

An unidentified person, who apparently collected the remains, gave the remains to the previous homeowner decades earlier. Osteological analysis arranged by the county sheriff determined that they are of Native American ancestry.

Determinations Made by History Colorado

Officials at History Colorado have determined that:

- Pursuant to 25 U.S.C. 3001(9)–(10), the human remains described above represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001 (2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains described above and any present-day Indian tribe.

History Colorado has determined that the human remains are ''culturally unidentifiable'' under NAGPRA, 43 CFR 10.9 (e)(6). In 2006, History Colorado, in partnership with the Colorado Commission of Indian Affairs, Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah conducted consultations with the tribes that have ancestral ties to the state of Colorado to develop the process for disposition of culturally unidentifiable Native American human remains and associated funerary objects originating from inadvertent discoveries on Colorado state and private lands. As a result of the consultation, a process was developed, titled: *Process for Consultation, Transfer, and Reburial of Culturally Unidentifiable Native American Human Remains and Associated Funerary Objects Originating From Inadvertent Discoveries on Colorado State and Private Lands* (2008) (unpublished, on file with the Colorado Office of Archaeology and Historic Preservation). The remains described above were recovered from the Basin and Plateau Consultation Region, as established by the *Process,* and tribes consulted are those who have expressed their wishes to be notified of discoveries in this region.

The Native American Graves Protection and Repatriation Review Committee (Review Committee) is responsible for recommending specific actions for disposition of culturally unidentifiable human remains. On November 3–4, 2006, the *Process* was presented to the Review Committee for consideration. A January 8, 2007 letter on behalf of the Review Committee from the Designated Federal Officer transmitted the provisional authorization to proceed with the *Process* upon receipt of formal responses from the Jicarilla Apache Nation, New Mexico, and Kiowa Indian Tribe of Oklahoma, and subject to forthcoming conditions imposed by the Secretary of the Interior. On May 15–16, 2008, the responses from the Jicarilla Apache Nation, New Mexico, and Kiowa Indian Tribe of Oklahoma were submitted to the Review Committee. On September 23, 2008, the Assistant Secretary for Fish and Wildlife and Parks, as the designee for the Secretary

of the Interior, transmitted the authorization for the disposition of culturally unidentifiable human remains according to the *Process* and NAGPRA, pending publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

43 CFR 10.11 was promulgated March 15, 2010, providing a process for the disposition of culturally unidentifiable Native American human remains recovered from tribal or aboriginal lands as established by the final judgment of the Indian Claims Commission or U.S. Court of Claims, a treaty, Act of Congress, or Executive Order, or other authoritative governmental sources. There is no evidence indicating that the human remains reported in this notice originated from tribal or aboriginal lands, making them eligible for disposition under the *Process.*

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Sheila Goff, NAGPRA Liaison, History Colorado, 1200 Broadway, Denver, CO 80203, telephone (303) 866–4531, before April 6, 2012. Transfer of control of the human remains to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado, and the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah may proceed after that date if no additional claimants come forward.

History Colorado is responsible for notifying the Apache Tribe of Oklahoma; Arapahoe Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma; Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Comanche Nation, Oklahoma; Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Crow Tribe of Montana; Fort Sill Apache Tribe of Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Kewa Pueblo, New Mexico (formerly Pueblo of Santo Domingo); Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota; Ohkay Owingeh, New Mexico (formerly the Pueblo of San Juan); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes) (formerly Paiute Indian Tribe of Utah (Cedar City Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes)); Pawnee Nation of Oklahoma; Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; San Juan Southern Paiute Tribe of Arizona; Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho; Shoshone Tribe of the Wind River Reservation, Wyoming; Southern Ute Indian Tribe of the Southern Ute Indian Reservation, Colorado; Standing Rock Sioux Tribe of North & South Dakota; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah; Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakoni), Oklahoma; Ysleta Del Sur Pueblo of Texas; and the Zuni Tribe of the Zuni Reservation, New Mexico, that this notice has been published.

Dated: March 2, 2012

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–5587 Filed 3–6–12; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–489 and 731–TA–1201 (Preliminary)]

Drawn Stainless Steel Sinks From China; Institution and Scheduling of Preliminary Phase Antidumping and Countervailing Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigations Nos. 701–TA–489 and 731–TA–1201 (Preliminary) under sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from China of drawn stainless steel sinks, provided for in subheading 7324.10 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce extends the time for initiation pursuant to sections 702(c)(1)(B) or 732(c)(1)(B) of the Act (19 U.S.C. 1671a(c)(1)(B) or 1673a(c)(1)(B)), the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by April 16, 2012. The Commission's views are due at Commerce within five business days thereafter, or by April 23, 2012.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

DATES: *Effective Date:* March 1, 2012.

FOR FURTHER INFORMATION CONTACT: Stefania Pozzi Porter (202–205–3177) or Amy Sherman (202–205–3289), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background. These investigations are being instituted in response to a petition filed on March 1, 2012, by Elkay Manufacturing Company, Oak Brook, IL.

Participation in the investigations and public service list. Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in

sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list. Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference. The Commission's Director of Investigations has scheduled a conference in connection with these investigations for 9:30 a.m. on March 22, 2012, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Requests to appear at the conference should be filed with the Office of the Secretary (*William.Bishop@usitc.gov* and *Sharon.Bellamy@usitc.gov*) on or before March 20, 2012. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions. As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before March 27, 2012, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 FR 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov.*

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

Issued: March 1, 2012.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–5480 Filed 3–6–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Docket No. 2880]

Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same,* DN 2880; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Align Technology on March 1, 2012. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same. The complaint names as respondents Clearcorrect Pakistan (Private) Ltd. of Pakistan; and Clearcorrect Operating, LLC of TX.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 2880'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

Issued: March 1, 2012.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–5445 Filed 3–6–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that on March 2, 2012, a proposed Consent Decree was lodged with the United States District Court for the District of Massachusetts in *United States* v. *Charles Johnson, et al.,* Civil Action No. 99–12465–EFH.

The proposed Consent Decree would resolve the United States' claims against the defendants Charles Johnson, Genelda Johnson, Francis Vaner Johnson, and the Johnson Cranberries Limited Partnership (the ''defendants'') for violations of sections 301(a) and 404 of the Clean Water Act, 33 U.S.C. 1311(a) and 1344. The proposed Consent Decree requires the defendants to pay a civil penalty and implement restoration and mitigation measures to create and restore wetlands in southeastern Massachusetts and to restore and perform compensatory mitigation at three existing cranberry bogs known as the Log Swamp Bogs off Great Meadow Drive in Carver, Massachusetts. The proposed Consent Decree also requires the defendants to restore wetlands at a site near Cross Street in Carver, Massachusetts, and an area of Beaver Dam Brook, which is at the Cross Street site.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to Assistant United States Attorney George Henderson, 1 Courthouse Way, Suite 9200, Boston, Massachusetts, 02210, and should refer to *United States* v. *Charles Johnson, et al.,* Civil Action No. 99–12465–EFH, DJ # 90–5–1–1–05720.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of Massachusetts, 1 Courthouse Way, Suite 2300, Boston, Massachusetts 02210, and at Region 1 of the Environmental Protection Agency, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109–3912. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/Consent_Decrees.html.*

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment & Natural Resources Division.

[FR Doc. 2012–5505 Filed 3–6–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; National Center for Natural Products Research-NIDA Project

By Notice dated September 28, 2011, and published in the **Federal Register** on October 7, 2011, 76 FR 62449, National Center for Natural Products Research-NIDA MProject, University of Mississippi, 135 Coy Waller Lab Complex, University, Mississippi 38677, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to cultivate marihuana for the National Institute on Drug Abuse for research approved by the Department of Health and Human Services.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of National Center for Natural Products Research-NIDA MProject to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated National Center for Natural Products Research-NIDA MProject to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: February 29, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–5441 Filed 3–6–12; 8:45 am]

BILLING CODE 4410–09–P

FOREIGN CLAIMS SETTLEMENT COMMISSION

[F.C.S.C. Meeting and Hearing Notice No. 03–12]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, March 15, 2012:

10 a.m.—Issuance of Proposed Decisions in Claims Against Libya;

11 a.m.—Oral Hearings on Objection to Commission's Proposed Decisions in Claim No. LIB–II–123;

12 noon—LIB–II–168.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Judith H. Lock, Executive Officer, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. Telephone: (202) 616–6975.

Jaleh F. Barrett,

Chief Counsel.

[FR Doc. 2012–5653 Filed 3–5–12; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Advisory Board Meeting

TIME AND DATE: 8 a.m.–4:30 p.m. on Monday, April 02, 2012. 8 a.m.–12 p.m. on Tuesday, April 03, 2012.

PLACE: Federal Bureau of Prisons, 500 First Street NW., Washington, DC 20534, (202) 514–4222.

MATTERS TO BE CONSIDERED: Directors report; review of outcomes of November 2–3, 2011 Advisory Board Hearing (Shifting the Focus to Reshape Our Thinking Toward Performance Based Outcomes), presentations, future planning.

CONTACT PERSON FOR MORE INFORMATION: Thomas Beauclair, Deputy Director, (202) 307–3106, extension 44254.

Morris L. Thigpen, Sr.,

Director, National Institute of Corrections.

[FR Doc. 2012–5225 Filed 3–6–12; 8:45 am]

BILLING CODE 4410–36–M

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

Record of Vote of Meeting Closure

(Public Law 94–409) (5 U.S.C. Sec. 552b)

I, Isaac Fulwood, of the United States Parole Commission, was present at a meeting of said Commission, which started at approximately 12 p.m., on Thursday, February 9, 2012, at the U.S. Parole Commission, 90 K Street NE., Third Floor, Washington, DC 20530. The purpose of the meeting was to discuss an original jurisdiction case pursuant to 28 CFR section 2.27. Four Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of the General Counsel that this meeting may be closed by votes of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Isaac Fulwood, Cranston J. Mitchell, Patricia Cushwa and J. Patricia Wilson Smoot.

In witness whereof, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: February 10, 2012.

Isaac Fulwood,

Chairman, U.S. Parole Commission.

[FR Doc. 2012–5638 Filed 3–5–12; 4:15 pm]

BILLING CODE 4410–31–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Agriculture Workers Survey

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, ''National Agriculture Workers Survey,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Employment and Training Administration, Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/ Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The National Agriculture Workers Survey (NAWS) is an employment-based, annual survey of the demographic, employment, and health characteristics of hired crop farm workers, including workers brought to farms by labor intermediaries. Each year, approximately 1,500 workers are randomly selected for an interview. In addition, point of contact information is obtained from approximately 564 farms. Interviews are conducted three times per year to account for the seasonality of agricultural production and employment.

Several Federal agencies utilize the NAWS to meet their information collection needs. The Environmental Protection Agency, Office of Pesticide Programs (EPA–OPP), which has responsibility for assessing exposure to pesticides, is one such agency. With this submission, the DOL seeks OMB approval to administer seven new questions in the NAWS regarding the amount of time per day farm workers

are employed in specific crops and tasks, and farm workers' hygiene and clothes laundering practices. The information obtained from the proposed questions will improve the EPA–OPP's ability to characterize the patterns of exposure, better assess pesticide risks posed to farm workers, and develop improved training and educational programs to manage the risks associated with exposure.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under OMB Control Number 1205–0453. The current OMB approval is scheduled to expire on October 31, 2013. For additional information, see the related notice published in the **Federal Register** on April 5, 2011.

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should reference OMB Control Number 1205–0453. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment and Training Administration.

Title of Collection: National Agriculture Workers Survey.

OMB Control Number: 1205–0453.

Affected Public: Individuals or Households and Private Sector—Farms.

Total Estimated Number of Respondents: 2,064.

Total Estimated Number of Responses: 2,064.

Total Estimated Annual Burden Hours: 1,693.

Total Estimated Annual Other Costs Burden: $0.

Dated: March 1, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–5482 Filed 3–6–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States: 2012 Allowable Charges for Agricultural Workers' Meals and Travel Subsistence Reimbursement, Including Lodging

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice and clarification of policy.

SUMMARY: The Employment and Training Administration (ETA) of the Department of Labor (Department) is issuing this Notice to announce the allowable charges for 2012 that employers seeking H–2A workers may charge their workers when the employer provides three meals a day, and the maximum meal reimbursement which a worker with receipts may claim. The Department is also providing clarification on the issue of overnight lodging costs as part of required subsistence, where necessary.

DATES: *Effective Date:* This notice is effective *March 7, 2012.*

FOR FURTHER INFORMATION CONTACT: William L. Carlson, Ph.D., Administrator, Office of Foreign Labor Certification (OFLC), U.S. Department of Labor, Room C–4312, 200 Constitution Avenue NW., Washington, DC 20210. Telephone: 202–693–3010 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The United States (U.S.) Citizenship and Immigration Services of the Department of Homeland Security will not approve an employer's petition for the admission of H–2A nonimmigrant temporary agricultural workers in the U.S. unless the petitioner has received from the Department an H–2A labor certification. The H–2A labor certification provides that: (1) There are not sufficient U.S. workers who are able, willing, and qualified, and who will be available at the time and place needed to perform the labor or services involved in the petition; and (2) the employment of the foreign worker(s) in such labor or services will not adversely affect the wages and working conditions of workers in the U.S. similarly employed. 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184(c)(1), and 1188(a); 8 CFR 214.2(h)(5) and (6).

Allowable Meal Charge

Among the minimum benefits and working conditions which the Department requires employers to offer their U.S. and H–2A workers are three meals a day or free and convenient cooking and kitchen facilities. 20 CFR 655.122(g). Where the employer provides the meals, the job offer must state the charge, if any, to the worker for such meals.

The Department provides, at 20 CFR 655.173(a), the methodology for determining the maximum amounts that H–2A agricultural employers may charge their U.S. and foreign workers for providing them with three meals per day. This methodology provides for annual adjustments of the previous year's maximum allowable charge based upon updated Consumer Price Index (CPI) data. The maximum charge allowed by 20 CFR 655.122(g) is adjusted by the same percentage as the 12 month percent change in the CPI for all Urban Consumers for Food (CPI–U for Food). The OFLC Certifying Officer may also permit an employer to charge workers a higher amount for providing them with three meals a day, if the higher amount is justified and sufficiently documented by the employer, as set forth in 20 CFR 655.173(b).

The Department has determined the percentage change between December of 2010 and December of 2011 for the CPI–U for Food was 3.7 percent. Accordingly, the maximum allowable charge under 20 CFR 655.122(g) shall be no more than $11.13 per day, unless the OFLC Certifying Officer approves a higher charge as authorized under 20 CFR 655.173(b).

Reimbursement for Daily Travel Subsistence

The regulations at 20 CFR 655.122(h) establish that the minimum daily travel subsistence expense, for which a worker

is entitled to reimbursement, is equivalent to the employer's daily charge for three meals or, if the employer makes no charge, the amount permitted under 20 CFR 655.122(g).

The maximum meals component of the daily travel subsistence expense is based upon the standard minimum Continental United States (CONUS) per diem rate as stated by the General Services Administration (GSA) at 41 CFR part 301, Appendix A. The CONUS meal component remains $46.00 per day. Workers who qualify for travel reimbursement are entitled to reimbursement for meals up to the CONUS meal rate when they provide receipts. In determining the appropriate amount of reimbursement for meals for less than a full day, the employer may provide for meal expense reimbursement, with receipts, to 75 percent of the maximum reimbursement for meals of $34.50, as provided for in the GSA per diem schedule. If a worker has no receipts, the employer is not obligated to reimburse above the minimum stated at 20 CFR 655.122(g) as specified above.

The Department notes that the regulation has consistently used the term ''subsistence'' which includes both meals and lodging during travel to and from the worksite. An employer is responsible for providing, paying in advance, or reimbursing a worker for the reasonable costs of transportation and daily subsistence between the employer's worksite and the place from which the worker comes to work for the employer, if the worker completes 50 percent of the work contract period, and upon the worker completing the contract, return costs. In those instances where a worker must travel to obtain a visa so that the worker may enter the U.S. to come to work for the employer, the employer must pay for the transportation and daily subsistence costs of that part of the travel as well. The Department interprets the regulation to require the employer to assume responsibility for the reasonable costs associated with the worker's travel, including transportation, food, and, in those instances where it is necessary, lodging. If not provided by the employer, the amount an employer must pay for transportation and, where required, lodging must be no less than (and is not required to be more than) the most economical and reasonable costs. The employer is responsible for those costs necessary for the worker to travel to the worksite if the worker completes 50 percent of the work contract period, but is not responsible for unauthorized detours, and if the worker completes the contract, return transportation and subsistence costs, including lodging costs where necessary. This policy applies equally to instances where the worker is traveling within the U.S. to the employer's worksite. For further information on when the employer is responsible for lodging costs, see the FAQ on travel costs at the OFLC Web site at *http://www.foreignlaborcert.doleta.gov/*.

Signed in Washington, DC, this 2nd day of March, 2012.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2012–5602 Filed 3–5–12; 11:15 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Division of Coal Mine Workers' Compensation; Proposed Extension of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Notice of Termination, Suspension, Reduction or Increase in Benefit Payments (CM–908). A copy of the information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before May 7, 2012.

ADDRESSES: Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0701, fax (202) 693–1447, Email *yoonferguson@dol.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION:

I. Background: The Office of Workers' Compensation Programs (OWCP)administers the Federal Mine Safety and Health Act of 1977 as amended, Section 432 (30 U.S.C. 942) and 20 CFR 725.621 necessitate this information collection. Under this Act, Coal mine operators, their representatives, or their insurers who have been identified as responsible for paying Black Lung benefits to an eligible miner or an eligible surviving dependent of the miner, are called Responsible Operators (RO's). RO's that pay benefits are required to report any change in the benefit amount to the Department of Labor (DOL). The CM–908, when completed and sent to DOL, notifies DOL of the change in the beneficiary's benefit amount and the reason for the change. The Federal Mine Safety and Health Act of 1977 as amended, Section 432 (30 U.S.C. 942) and 20 CFR 725.621 necessitate this information collection. This information collection is currently approved for use through June 30, 2012.

II. Review Focus: The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* Enhance the quality, utility and clarity of the information to be collected; and

* Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions: The Department of Labor seeks the approval for the extension of this currently-approved information collection in order to carry out its responsibility to evaluate an applicant ability to be a representative payee. If the Program were not able to screen representative payee applicants the beneficiary's best interest would not be served.

Agency: Office of Workers' Compensation Programs.

Type of Review: Extension.

Title: Notice of Termination, Suspension, Reduction or Increase in Benefit Payments.

OMB Number: 1240–0030.

Agency Number: CM–908.

Affected Public: Business or other for profit.

Total Respondents: 325.

Total Annual Responses: 5,000.

Average Time per Response: 12 minutes.

Estimated Total Burden Hours: 1,000.

Frequency: On occasion and annually.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $4,800.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: March 2, 2012.

Vincent Alvarez,

Agency Clearance Officer, Office of Workers' Compensation Programs, US Department of Labor.

[FR Doc. 2012–5572 Filed 3–6–12; 8:45 am]

BILLING CODE 4510–CK–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 12–02]

Notice of Quarterly Report (October 1, 2011–December 31, 2011)

AGENCY: Millennium Challenge Corporation.

SUMMARY: The Millennium Challenge Corporation (MCC) is reporting for the quarter October 1, 2011 through December 31, 2011, on assistance provided under section 605 of the Millennium Challenge Act of 2003 (22 U.S.C. 7701 *et seq.*), as amended (the Act), and on transfers or allocations of funds to other federal agencies under section 619(b) of the Act. The following report will be made available to the public by publication in the **Federal Register** and on the Internet Web site of the MCC (*www.mcc.gov*) in accordance with section 612(b) of the Act.

Dated: March 1, 2012.

T. Charles Cooper,

Vice President, Congressional and Public Affairs, Millennium Challenge Corporation.

ASSISTANCE PROVIDED UNDER SECTION 605

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Madagascar Year: 2012 Quarter 1 Total Obligation: $84,367,700 Entity to which the assistance is provided: MCA Madagascar Total Quarterly Expenditures [1]: $0				
Land Tenure Project	$29,470,242	*Increase Land Titling and Security.*	$29,304,770	Area secured with land certificates or titles in the Zones. Legal and regulatory reforms adopted. Number of land documents inventoried in the Zones and Antananarivo. Number of land documents restored in the Zones and Antananarivo. Number of land documents digitized in the Zones and Antananarivo. Average time for Land Services Offices to issue a duplicate copy of a title. Average cost to a user to obtain a duplicate copy of a title from the Land Services Offices. Number of land certificates delivered in the Zones during the period. Number of new *guichets fonciers* operating in the Zones. The 256 *Plan Local d'Occupation Foncier*—Local Plan of Land Occupation (PLOFs)are completed.
Financial Sector Reform Project.	$23,535,781	*Increase Competition in the Financial Sector.*	$23,535,781	Volume of funds processed annually by the national payment system. Number of accountants and financial experts registered to become CPA. Number of Central Bank branches capable of accepting auction tenders. Outstanding value of savings accounts from CEM in the Zones. Number of Micro-Finance Institutions (MFIs) participating in the Refinancing and Guarantee funds. Maximum check clearing delay. Network equipment and integrator. Real time gross settlement system (RTGS). Telecommunication facilities. Retail payment clearing system. Number of CEM branches built in the Zones. Number of savings accounts from CEM in the Zones. Percent of Micro-Finance Institution (MFI) loans recorded in the Central Bank database.

ASSISTANCE PROVIDED UNDER SECTION 605—Continued

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Agricultural Business Investment Project.	$13,582,551	*Improve Agricultural Projection Technologies and Market Capacity in Rural Areas.*	$13,582,534	Number of farmers receiving technical assistance. Number of marketing contracts of ABC clients. Number of farmers employing technical assistance. Value of refinancing loans and guarantees issued to participating MFIs (as a measure of value of agricultural and rural loans). Number of Mnistère de l'Agriculture,de l'Elevage et de la Pêche—Ministry of Agriculture, Livestock, and Fishing (MAEP) agents trained in marketing and investment promotion. Number of people receiving information from Agricultural Business Center (ABCs) on business opportunities.
Program Administration[2] and Control, Monitoring and Evaluation.	$17,779,127	.....	$17,779,126	
Pending subsequent reports.[3]		.....	$1,392,568	

The compact indicated is closed and therefore will not have any quarterly expenditure amount.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Honduras Year: 2012 Quarter 1 Total Obligation: $205,000,000 Entity to which the assistance is provided: MCA Honduras Total Quarterly Expenditures[1]: $0				
Rural Development Project	$68,273,380	*Increase the productivity and business skills of farmers who operate small and medium-size farms and their employees.*	$68,264,510	Number of program farmers harvesting high-value horticulture crops. Number of hectares harvesting high-value horticulture crops. Number of business plans prepared by program farmers with assistance from the implementing entity. Total value of net sales. Total number of recruited farmers receiving technical assistance. Value of loans disbursed to farmers, agribusiness, and other producers and vendors in the horticulture industry, including Program Farmers, cumulative to date, Trust Fund Resources. Number of loans disbursed (disaggregated by trust fund, leveraged from trust fund, and institutions receiving technical assistance from ACDI–VOCA). Number of hectares under irrigation. Number of farmers connected to the community irrigation system
Transportation Project	$120,591,240	*Reduce transportation costs between targeted production centers and national, regional and global markets.*	$120,584,457	Freight shipment cost from Tegucigalpa to Puerto Cortes. Average annual daily traffic volume—CA–5. International roughness index (IRI)—CA–5. Kilometers of road upgraded—CA–5. Percent of contracted road works disbursed—CA–5. Average annual daily traffic volume—secondary roads. International roughness index (IRI)—secondary roads. Kilometers of road upgraded—secondary roads. Average annual daily traffic volume—rural roads. Average speed—Cost per journey (rural roads). Kilometers of road upgraded—rural roads. Percent disbursed for contracted studies. Value of signed contracts for feasibility, design, supervision and program management contracts. Kilometers (km) of roads under design. Number of Construction works and supervision contracts signed. Kilometers (km) of roads under works contracts.
Program Administration,[2] and Control, Monitoring and Evaluation.	$16,135,380	.....	$15,166,048	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Pending subsequent reports.[3]		.....	$0	

The compact indicated is closed and therefore will not have any quarterly expenditure amount.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Cape Verde Year: 2012 Quarter 1 Total Obligation: $110,078,488 Entity to which the assistance is provided: Cape Verde Total Quarterly Expenditures[1]: $0				
Watershed and Agricultural Support Project.	$12,011,603	*Increase agricultural production in three targeted watershed areas on three islands.*	$11,602,406	Productivity: Horticulture, Paul watershed. Productivity: Horticulture, Faja watershed. Productivity: Horticulture, Mosteiros watershed. Number of farmers adopting drip irrigation: All intervention watersheds (Paul, Faja and Mosteiros). Hectares under improved or new irrigation (All Watersheds Paul, Faja, and Mosteiros). Irrigation Works: Percent contracted works disbursed. All intervention watersheds (Paul, Faja and Mosteiros). Number of reservoirs constructed in all intervention watersheds (Paul, Faja and Mosteiros) (incremental). Number of farmers trained.
Infrastructure Improvement Project.	$82,630,208	*Increase integration of the internal market and reduce transportation costs.*	$82,542,708	Travel time ratio: percentage of beneficiary population further than 30 minutes from nearest market. Kilometers of roads/bridges completed. Percent of contracted road works disbursed (cumulative). Port of Praia: percent of contracted port works disbursed (cumulative).
Private Sector Development Project.	$1,920,018	*Spur private sector development on all islands through increased investment in the priority sectors and through financial sector reform.*	$1,824,566	Micro-Finance Institutions portfolio at risk, adjusted (level).
Program Administration,[2] and Control, Monitoring and Evaluation.	$13,516,659	.....	$12,542,777	
Pending subsequent reports.[3]			$0	

The compact indicated is closed and therefore will not have any quarterly expenditure amount.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Nicaragua Year: 2012 Quarter 1 Total Obligation: $112,099,390 Entity to which the assistance is provided: MCA Nicaragua Total Quarterly Expenditures: $ −44,742				
Property Regularization Project.	$7,180,454	*Increase Investment by strengthening property rights.*	$6,713,554	Automated database of registry and cadastre installed in the 10 municipalities of Leon. Value of land, urban. Value of land, rural. Time to conduct a land transaction. Number of additional parcels with a registered title, urban. Number of additional parcels with a registered title, rural. Area covered by cadastral mapping. Cost to conduct a land transaction.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Transportation Project	$57,735,608	Reduce transportation costs between Leon and Chinandega and national, regional and global markets.	$56,740,790	Annual Average daily traffic volume: N1 Section R1. Annual Average daily traffic volume: N1 Section R2. Annual Average daily traffic volume: Port Sandino (S13). Annual Average daily traffic volume: Villanueva—Guasaule Annual. Average daily traffic volume: Somotillo-Cinco Pinos (S1). Annual average daily traffic volume: León-Poneloya-Las Peñitas. International Roughness Index: N–I Section R1. International Roughness Index: N–I Section R2. International Roughness Index: Port Sandino (S13). International roughness index: Villanueva—Guasaule. International roughness index: Somotillo-Cinco Pinos. International roughness index: León-Poneloya-Las Peñitas. Kilometers of NI upgraded: R1 and R2 and S13. Kilometers of NI upgraded: Villanueva—Guasaule. Kilometers of S1 road upgraded. Kilometers of S9 road upgraded.
Rural Development Project	$31,530,722	*Increase the value added of farms and enterprises in the region.*	$31,291,352	Number of beneficiaries with business plans. Numbers of *manzanas (1 manzana = 1.7 hectares),* by sector, harvesting higher-value crops. Number of beneficiaries with business plans prepared with assistance of Rural Business Development Project. Number of beneficiaries implementing forestry business plans under Improvement of Water Supplies Activity. Number of Manzanas reforested. Number of Manzanas with trees planted.
Program Administration,[2] Due Diligence, Monitoring and Evaluation.	$15,562,106	.....	$15,300,819	
Pending subsequent reports.[3]		.....	$2,685,101	

The negative quarterly expenditure for Nicaragua is due to a return of funds to the permitted account for compact closure.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Georgia Year: 2012 Quarter 1 Total Obligation: $395,300,000 Entity to which the assistance is provided: Georgia Total Quarterly Expenditures [1]: $0				
Regional Infrastructure Rehabilitation Project.	$314,240,000	*Key Regional Infrastructure Rehabilitated.*	$314,240,000	Household savings from Infrastructure Rehabilitation Activities. Savings in vehicle operating costs (VOC). International roughness index (IRI). Annual average daily traffic (AADT). Travel Time. Kilometers of road completed. Signed contracts for feasibility and/or design studies. Percent of contracted studies disbursed. Kilometers of roads under design. Signed contracts for road works. Kilometers of roads under works contracts. Sites rehabilitated (phases I, II, III)—pipeline. Construction works completed (phase II)—pipeline. Savings in household expenditures for all RID subprojects. Population Served by all RID subprojects. RID Subprojects completed. Value of Grant Agreements signed. Value of project works and goods contracts Signed. Subprojects with works initiated.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Regional Enterprise Development Project.	$52,040,800	*Enterprises in Regions Developed.*	$48,899,625	Jobs Created by Agribusiness Development Activity (ADA) and by Georgia Regional Development Fund (GRDF). Household net income—ADA and GRDF. Jobs created—ADA. Firm income—ADA. Household net income—ADA. Beneficiaries (direct and indirect)—ADA. Grant agreements signed—ADA. Increase in gross revenues of portfolio companies. Increase in portfolio company employees. Increase in wages paid to the portfolio company employees. Portfolio companies. Funds disbursed to the portfolio companies.
Program Administration[2], Due Diligence, Monitoring and Evaluation.	$29,019,200	.....	$24,038,894	
Pending subsequent reports.[3]		.....	$1	

In November 2008, MCC and the Georgian government signed a Compact amendment making up to $100 million of additional funds available under the Compact to complete works in the Roads, Regional Infrastructure Development, and Energy Rehabilitation Projects contemplated by the original Compact. The amendment was ratified by the Georgian parliament and entered into force on January 30, 2009.

The compact indicated is closed and therefore will not have any quarterly expenditure amount.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Vanuatu Year: 2012 Quarter 1 Total Obligation: $65,690,000 Entity to which the assistance is provided: Vanuatu Total Quarterly Expenditures: $ − 119,936				
Transportation Infrastructure Project.	$60,096,085	*Facilitate transportation to increase tourism and business development.*	$60,078,180	Traffic volume (average annual daily traffic)—Efate Ring Road. Traffic Volume (average annual daily traffic)—Santo East Coast Road. Kilometers of road upgraded—Efate Ring Road. Kilometers of roads upgraded—Santo East Coast Road. Percent of MCC contribution disbursed to "adjusted" signed contracts of roads works; including approved variations.
Program Administration,[2] Due Diligence, Monitoring and Evaluation.	$5,593,915	.....	$5,319,220	
Pending subsequent reports.[3]		.....	$6,117	

The negative quarterly expenditure for Vanuatu is due to a return of funds to the permitted account for compact closure.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Armenia Year: 2012 Quarter 1 Total Obligation: $177,650,000 Entity to which the assistance is provided: MCA Armenia Total Quarterly Expenditures [1]: $430,535				
Irrigated Agriculture Project (Agriculture and Water).	$153,892,467	*Increase agricultural productivity Improve and Quality of Irrigation*.	$138,270,503	Training/technical assistance provided for On-Farm Water Management. Training/technical assistance provided for Post-Harvest Processing. Loans Provided. Value of irrigation feasibility and/or detailed design contracts signed. Value of irrigation feasibility and/or detailed design contracts disbursed. Number of farmers using better on-farm water management. Number of enterprises using improved techniques. Value of irrigation feasibility and/or detailed design contracts signed. Additional Land irrigated under project. Value of irrigation feasibility and/or detailed design contracts signed. Value of irrigation feasibility and/or detailed design contracts disbursed.
Rural Road Rehabilitation Project.	$9,100,000	*Better access to economic and social infrastructure*.	$8,441,028	Average annual daily traffic on Pilot Roads. International roughness index for Pilot Roads. Road Sections Rehabilitated—Pilot Roads. Pilot Roads: Percent of Contracted Roads Works Disbursed of Works Completed.
Program Administration,[2] Due Diligence, Monitoring and Evaluation.	$14,657,533	.....	$12,655,852	
Pending subsequent reports.[3]		.....	$17,268,594	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Benin Year: 2012 Quarter 1 Total Obligation: $307,298,039 Entity to which the assistance is provided: MCA Benin Total Quarterly Expenditures [1]: $12,613,044				
Access to Financial Services Project.	$17,688,674	*Expand Access to Financial Services*.	$15,677,863	Value of credits granted by Micro-Finance Institutions (at the national level). Value of savings collected by MFI institutions (at the national level). Average portfolio at risk >90 days of microfinance institutions at the national level. Operational self-sufficiency of MFIs at the national level. Number of institutions receiving grants through the Facility. Number of MFIs *inspected by Cellule Supervision Microfinance*.
Access to Justice Project ..	$20,075,580	*Improved Ability of Justice System to Enforce Contracts and Reconcile Claims*.	$18,906,218	Average time to enforce a contract. Percent of firms reporting confidence in the judicial system. Passage of new legal codes. Average time required for Tribunaux de premiere instance- arbitration centers and courts of first instance (TPI) to reach a final decision on a case. Average time required for Court of Appeals to reach a final decision on a case. Percent of cases resolved in TPI per year. Percent of cases resolved in Court of Appeals per year. Number of Courthouses completed. Average time required to register a business (*société*). Average time required to register a business (sole proprietorship).

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Access to Land Project	$32,182,938	*Strengthen property rights and increase investment in rural and urban land.*	$31,431,243	Percentage of households investing in targeted urban land parcels. Percentage of households investing in targeted rural land parcels Average cost required to convert occupancy permit to land title through systematic process. Share of respondents perceiving land security in the Conversions from Occupancy permit to land title (PH–TF) or Rural Land Plan (PFR) areas. Number of preparatory studies completed. Number of Legal and Regulatory Reforms Adopted. Amount of Equipment Purchased. Number of new land titles obtained by transformation of occupancy permit. Number of land certificates issued within MCA-Benin implementation. Number of PFRs established with MCA Benin implementation. Number of permanent stations installed. Number of stakeholders Trained. Number of communes with new cadastres. Number of operational land market information systems.
Access to Markets Project	$188,866,208	*Improve Access to Markets through Improvements to the Port of Cotonou.*	$186,267,744	Volume of merchandise traffic through the Port Autonome de Cotonou. Bulk ship carriers waiting times at the port. Port design-build contract awarded. Annual number of thefts cases. Average time to clear customs. Port meets—international port security standards (ISPS).
Program Administration[2], Due Diligence, Monitoring and Evaluation.	$48,484,639	.....	$45,094,520	
Pending subsequent reports.[3]		.....	$26,162	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Ghana Year: 2012 Quarter 1 Total Obligation: $547,009,000 Entity to which the assistance is provided: MCA Ghana Total Quarterly Expenditures [1]: $44,927,875				
Agriculture Project	$208,764,152	*Enhance Profitability of cultivation, services to agriculture and product handling in support of the expansion of commercial agriculture among groups of smallholder farms.*	$200,146,626	Number of farmers trained in commercial agriculture. Number of agribusinesses assisted. Number of preparatory land studies completed. Legal and regulatory land reforms adopted. Number of landholders reached by public outreach efforts. Number of hectares under production. Number of personnel trained. Number of buildings rehabilitated/constructed. Value of equipment purchased. Feeder roads international roughness index. Feeder roads annualized average daily traffic. Value of signed contracts for feasibility and/or design studies of feeder roads. Percent of contracted design/feasibility studies completed for feeder roads. Value of signed works contracts for feeder roads. Percent of contracted feeder road works disbursed. Value of loans disbursed to clients from agriculture loan fund. Value of signed contracts for feasibility and/or design studies (irrigation). Percent of contracted (design/feasibility) studies complete (irrigation). Value of signed contracts for irrigation works (irrigation). Rural hectares mapped. Percent of contracted irrigation works disbursed. Percent of people aware of their land rights in Pilot Land Registration Areas. Total number of parcels surveyed in the Pilot Land Registration Areas (PLRAs). Volume of products passing through post-harvest treatment.
Rural Development Project	$74,662,857	*Strengthen the rural institutions that provide services complementary to, and supportive of, agricultural and agriculture business development.*	$69,078,664	Number of students enrolled in schools affected by Education Facilities Sub-Activity. Number of schools rehabilitated. Number of school blocks constructed. Distance to collect water. Time to collect water. Incidence of guinea worm. Number of people affected by Water and Sanitation Facilities Sub-Activity. Number of stand-alone boreholes/wells/nonconventional water systems constructed/rehabilitated. Number of small-town water systems designed and due diligence completed for construction. Number of pipe extension projects designed and due diligence completed for construction. Number of agricultural processing plants in target districts with electricity due to Rural Electrification Sub-Activity.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Transportation Project	$218,367,447	*Reduce the transportation costs affecting agriculture commerce at sub-regional levels.*	$199,628,657	Trunk roads international roughness index. N1 International roughness index. N1 Annualized average daily traffic. N1 Kilometers of road upgraded. Value of signed contracts for feasibility and/or design studies of the N1. Percent of contracted design/feasibility studies completed of the N1. Value of signed contracts for road works N1, Lot 1. Value of signed contracts for road works N1, Lot 2. Trunk roads annualized average daily traffic. Trunk roads kilometers of roads completed. Percent of contracted design/feasibility studies completed of trunk roads. Percent of contracted trunk road works disbursed. Ferry Activity: annualized average daily traffic vehicles. Ferry Activity: annual average daily traffic (passengers). Landing stages rehabilitated. Ferry terminal upgraded. Rehabilitation of Akosombo Floating Dock completed. Rehabilitation of landing stages completed. Percent of contracted road works disbursed: N1, Lot 2. Percent of contracted road works disbursed: N1, Lot 2. Percent of contracted work disbursed: ferry and floating dock. Percent of contracted work disbursed: landings and terminals. Value of signed contracts for feasibility and/or design studies of Trunk Roads. Value of signed contracts for trunk roads.
Program Administration,[2] Due Diligence, Monitoring and Evaluation.	$45,214,544	.....	$36,056,644	
Pending subsequent reports.[3].		.....	$70,168	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: El Salvador Year: 2012 Quarter 1 Total Obligation: $460,939,000 Entity to which the assistance is provided: MCA El Salvador Total Quarterly Expenditures [1]: $33,535,619				
Human Development Project.	$89,146,523	*Increase human and physical capital of residents of the Northern Zone to take advantage of employment and business opportunities.*	$68,037,654	Employment rate of graduates of middle technical schools. Graduation rates of middle technical schools. Middle technical schools remodeled and equipped. New Scholarships granted to students of middle technical education. Students of non-formal training. Cost of water. Time collecting water. Number of households with access to improved water supply. Value of contracted water and sanitation works disbursed. Cost of electricity. Households benefiting with a connection to the electricity network. Household benefiting with the installation of isolated solar systems. Kilometers of new electrical lines with construction contracts signed. Population benefiting from strategic infrastructure.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Productive Development Project.	$71,824,000	*Increase production and employment in the Northern Zone..*	$26,483,228	Number of hectares under production with MCC support. Number of beneficiaries of technical assistance and training—Agriculture. Number of beneficiaries of technical assistance and training—Agribusiness. Value of agricultural loans to farmers/agribusiness.
Connectivity Project	$268,891,273	*Reduce travel cost and time within the Northern Zone, with the rest of the country, and within the region..*	$188,845,875	Average annual daily traffic. International roughness index. Kilometers of roads rehabilitated. Kilometers of roads with construction initiated.
Productive Development Project.	$68,536,736	.....	$57,013,980	
Program Administration [2] and Control, Monitoring and Evaluation.	$34,365,368	.....	$23,022,526	
Pending Subsequent Report.[3].		.....	$0	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Mali Year: 2012 Quarter 1 Total Obligation: $460,811,163 Entity to which the assistance is provided: MCA Mali Total Quarterly Expenditures [1]: $37,913,577				
Bamako-Senou Airport Improvement Project.	$176,252,117	.....	$91,093,202	Number of full time jobs at the ADM and firms supporting the airport. Average number of weekly flights(arrivals). Passenger traffic (annual average). Percent works complete. Time required for passenger processing at departures and arrivals. Percent works complete. Security and safety deficiencies corrected at the airport.
Alatona Irrigation Project.	$239,884,675	*Increase the agricultural production and productivity in the Alatona zone of the ON.*	$223,821,509	Main season rice yields. International roughness index (IRI) on the Niono-Goma Coura Route. Traffic on the Niono-Diabaly road segment. Traffic on the Diabaly-Goma Coura road segment. Percentage works completed on Niono-Goma Coura road. Hectares under improved irrigation. Irrigation system efficiency on Alatona Canal. Percentage of contracted irrigation construction works disbursed. Number market gardens allocated in Alatona zones to PAPs or New Settler women. Net primary school enrollment rate (in Alatona zone). Percent of Alatona population with improved access to drinking water. Number of schools available in Alatona. Number of health centers available in the Alatona. Number of affected people who have been compensate. Number of farmers that have applied improved techniques. Hectares under production (rainy season). Hectares under production (dry season). Number of farmers trained. Value of agricultural and rural loans. Number of active MFI clients. Loan recovery rate among Alatona farmers.
Industrial Park Project	$2,637,472	*Terminated*	$2,637,472	
Program Administration [2] and Control, Monitoring and Evaluation.	$42,036,899	.....	$31,097,194	
Pending Subsequent Report.[3].	.....	.....	$778,555	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Mongolia Year: 2012 Quarter 1 Total Obligation: $284,911,363 Entity to which the assistance is provided: MCA Mongolia Total Quarterly Expenditures [1]: $27,952,192				
Property Rights Project	$27,202,619	*Increase security and capitalization of land assets held by lower-income Mongolians, and increased peri-urban herder productivity and incomes.*	$13,027,788	Number of legal and regulatory framework or preparatory studies completed (Peri-Urban and Land Plots). Number of Legal and regulatory reforms adopted. Number of stakeholders (Peri-Urban and Land Plots). Stakeholders Trained (Peri-Urban and Land Plots). Number of Buildings Built/Rehabilitated. Equipment purchased. Rural hectares Mapped. Urban Parcels Mapped. Leaseholds Awarded.
Vocational Education Project.	$47,355,638	*Increase employment and income among unemployed and underemployed Mongolians.*	$21,999,427	Rate of employment. Vocational school graduates in MCC-supported educational facilities. Percent of active teachers receiving certification training. Technical and vocational education and training (TVET) legislation passed.
Health Project	$38,973,259	*Increase the adoption of behaviors that reduce non-communicable diseases (NCDIs) among target populations and improved medical treatment and control of NCDIs.*	$20,348,858	Treatment of diabetes. Treatment of hypertension. Early detection of cervical cancer. Recommendations on road safety interventions available.
Roads Project	$86,740,123	*More efficient transport for trade and access to services.*	$9,753,408	Kilometers of roads completed. Annual average daily traffic. Travel time. International Roughness Index. Kilometers of roads under design. Percent of contracted roads works disbursed.
Energy and Environmental Project.	$46,966,205	*Increased wealth and productivity through greater fuel use efficiency and decreasing health costs from air.*	$14,445,869	Household savings from decreased fuel costs. Product testing and subsidy setting process adopted. Health costs from air pollution in Ulaanbaatar. Reduced particulate matter concentration. Capacity of wind power generation.
Rail Project	$369,560	*Terminated*	$369,560	*Terminated.*
Program Administration [2] and Control, Monitoring and Evaluation.	$37,303,959	.....	$18,673,828	
Pending subsequent reports.[3].		.....	$451,192	

In late 2009, the MCC's Board of Directors approved the allocation of a portion of the funds originally designated for the rail project to the expansion of the health, vocational education and property right projects from the rail project, and the remaining portion to the addition of a road project.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Mozambique Year: 2012 Quarter 1 Total Obligation: $506,924,053 Entity to which the assistance is provided: MCA Mongolia Total Quarterly Expenditures [1]: $15,103,561				
Water Supply and Sanitation Project.	$207,385,393	*Increase access to reliable and quality water and sanitation facilities.*	$41,450,732	Percent of urban population with improved water sources. Time to get to non-private water source. Percent of urban population with improved sanitation facilities. Percent of rural population with access to improved water sources. Number of private household water connections in urban areas. Number of rural water points constructed. Number of standpipes in urban areas. Five cities: Final detailed design submitted. Three cities: Final detailed design submitted.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Road Rehabilitation Project	$176,307,480	*Increase access to productive resources and markets.*	$31,325,587	Kilometers of road rehabilitated. Namialo—Rio Lúrio Road—Metoro: Percent of feasibility, design, and supervision contract disbursed. Rio Ligonha-Nampula: Percent of feasibility, design, and supervision contract disbursed. Chimuara-Nicoadala: Percent of feasibility, design, and supervision contract disbursed. Namialo—Rio Lúrio: Percent of road construction contract disbursed. Rio Lúrio—Metoro: Percent of road construction contract disbursed. Rio Ligonha—Nampula: Percent of road construction contract disbursed. Chimuara-Nicoadala: Percent of road construction contract disbursed. Namialo-Rio Lúrio Road: Average annual daily traffic volume. Rio Lúrio-Metoro Road: Average annual daily traffic volume. Rio-Ligonha-Nampula Road: Average annual daily traffic volume. Chimuara-Nicoadala Road: Average annual daily traffic volume. Namialo-Rio Lúrio Road: Change in International Roughness Index (IRI). Rio Lúrio-Metoro Road: Change in International Roughness Index (IRI). Rio-Ligonha-Nampula Road: Change in International Roughness Index (IRI). Chimuara-Nicoadala Road: Change in International Roughness Index (IRI).
Land Tenure Project	$39,068,307	*Establish efficient, secure land access for households and investors.*	$15,251,547	Time to get land usage rights (DUAT), urban. Time to get land usage rights (DUAT), rural. Number of buildings rehabilitated or built. Total value of procured equipment and materials. Number of people trained. Rural hectares mapped in Site Specific Activity. Urban parcels mapped. Rural hectares formalized through Site Specific Activity. Urban parcels formalized. Number of communities delimited and formalized. Number of urban households having land formalized.
Farmer Income Support Project.	$18,400,117	*Improve coconut productivity and diversification into cash crop.*	$9,675,288	Number of diseased or dead palm trees cleared. Survival rate of Coconut seedlings. Hectares under production. Number of farmers trained in pest and disease control. Number of farmers trained in crop diversification technologies. Income from coconuts and coconut products (estates). Income from coconuts and coconuts products (households).
Program Administration [2] and Control, Monitoring and Evaluation.	$65,762,756	.....	$25,227,193	
Pending Subsequent Report.[3]		.....	$1,499,712	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Lesotho Year: 2012 Quarter 1 Total Obligation: $362,551,000 Entity to which the assistance is provided: MCA Lesotho Total Quarterly Expenditures [1]: $17,780,409				
Water Project	$164,027,999	*Improve the water supply for industrial and domestic needs, and enhance rural livelihoods through improved watershed management.*	$45,320,536	School days lost due to water borne diseases. Diarrhea notification at health centers. Households with access to improved water supply. Households with access to improved Latrines. Knowledge of good hygiene practices. Households with reliable water services. Enterprises with reliable water services. Households with reliable water services. Volume of treated water. Area re-vegetation.
Health Project	$122,398,000	*Increase access to life-extending ART and essential health services by providing a sustainable delivery platform.*	$60,811,339	People with HIV still alive 12 months after initiation of treatment. TB notification (per 100,000 pop.). People living with HIV/AIDS (PLWA) receiving Antiretroviral treatment. Deliveries conducted in the health facilities. Immunization coverage rate.
Private Sector Development Project.	$36,470,318	*Stimulate investment by improving access to credit, reducing transaction costs and increasing the participation of women in the economy.*	$11,680,282	Time required to enforce a contract. Value of commercial cases. Cases referred to Alternative Dispute Resolution (ADR) that are successfully completed. Portfolio of loans. Loan application processing time. Performing loans. Electronic payments—salaries. Electronic payments—pensions. Debit/smart cards issued. Mortgage bonds registered. Value of registered mortgage bonds. Clearing time—Country. Clearing time—Maseru. Land transactions recorded. Land parcels regularized and registered. People trained on gender equality and economic rights. Eligible population with ID cards. Monetary cost to process a lease application.
Program Administration [2] and Control, Monitoring and Evaluation.	$39,654,682	.....	$24,106,022	
Pending Subsequent Report.[3]		.....	$1,775,545	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Morocco Year: 2012 Quarter 1 Total Obligation: $697,500,000 Entity to which the assistance is provided: MCA Mongolia Total Quarterly Expenditures [1]: $49,280,154				
Fruit Tree Productivity Project.	$326,096,445	*Reduce volatility of agricultural production and increase volume of fruit agricultural production.*	$149,295,576	Number of farmers trained. Number of agribusinesses assisted. Number of hectares under production. Value of agricultural production.
Small Scale Fisheries Project.	$120,668,028	*Improve quality of fish moving through domestic channels and assure the sustainable use of fishing resources.*	$14,878,156	Landing sites and ports rehabilitated. Mobile fish vendors using new equipment. Fishing boats using new landing sites. Average price of fish at auction markets. Average price of fish at wholesale. Average price of fish at ports.
Artisan and Fez Medina Project.	$93,523,859	*Increase value added to tourism and artisan sectors.*	$15,965,339	Average revenue of Small and Micro Enterprise (SME) pottery workshops. Construction and rehabilitation of Fez Medina Sites. Tourist receipts in Fez. Training of potters.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Enterprise Support Project	$31,000,000	*Improved survival rate of new SMEs and INDH-funded income generating activities; increased revenue for new SMEs and INDH-funded income generating activities.*	$12,150,300	Value added per enterprise. Survival rate after two years.
Financial Services Project	$43,700,000	*To be determined ("TBD").*	$25,981,614	Portfolio at risk at 30 days. Portfolio rate of return. Number of clients of Microcredit Associations (AMCs) reached through mobile branches.
Program Administration [2] and Control, Monitoring and Evaluation.	$82,511,669	.....	$43,417,661	
Pending Subsequent Report.[3]		.....	$6,883,623	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Tanzania Year: 2012 Quarter 1 Total Obligation: $692,135,920 Entity to which the assistance is provided: MCA Tanzania Total Quarterly Expenditures [1]: $93,678,206				
Energy Sector Project	$203,516,606	*Increase value added to businesses.*	$124,634,658	Current power customers: Morogoro D1, Morogoro T1, Morogoro T2 & T3, Tanga D1, Tanga T1, Tanga T2 & T3, Mbeya D1, Mbeya T1, Mbeya T2 & T3, Iringa D1, Iringa T1, Iringa T2 & T3, Dodoma D1, Dodoma T1, Dodoma T2 & T3, Mwanza D1, Mwanza T1 and Mwanza T2 & T3. Transmission and distribution sub-station capacity: Morogoro, Tanga, Mbeya, Iringa, Dodoma and Mwanza. Collection efficiency (Morogoro). Collection efficiency (Tanga). Collection efficiency (Mbeya). Collection efficiency (Iringa). Collection efficiency (Dodoma). Collection efficiency (Mwanza). Technical and nontechnical losses (Morogoro). Technical and nontechnical losses (Tanga). Technical and nontechnical losses (Mbeya). Technical and nontechnical losses (Iringa). Technical and nontechnical losses (Dodoma). Technical and nontechnical losses (Mwanza).

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Transport Sector Project ...	$368,826,391	*Increase cash crop revenue and aggregate visitor spending.*	$194,470,026	International roughness index: Tunduma Sumbawanga. International roughness index: Tanga Horohoro. International roughness index: Namtumbo Songea. International roughness index: Peramiho Mbinga. Annual average daily traffic: Tunduma Sumbawanga. Annual average daily traffic: Tanga Horohoro. Annual average daily traffic: Namtumbo Songea. Annual average daily traffic: Peramiho Mbinga. Kilometers upgraded/completed: Tunduma Sumbawanga. Kilometers upgraded/completed: Tanga Horohoro. Kilometers upgraded/completed: Namtumbo Songea. Kilometers upgraded/completed: Peramiho Mbinga. Percent disbursed on construction works: Tunduma Sumbawanga. Percent disbursed on construction works: Tanga Horohoro. Percent disbursed on construction works: Namtumbo Songea. Percent disbursed on construction works: Peramiho Mbinga. Percent disbursed for feasibility and/or design studies: Tunduma Sumbawanga. Percent disbursed for feasibility and/or design studies: Tanga Horohoro. Percent disbursed for feasibility and/or design studies: Namtumbo Songea. Percent disbursed for feasibility and/or design studies: Peramiho Mbinga. International roughness index: Pemba. Average annual daily traffic: Pemba. Kilometers upgraded/completed: Pemba. Percent disbursed on construction works: Pemba. Signed contracts for construction works (Zanzibar Rural Roads). Percent disbursed on signed contracts for feasibility and/or design studies: Pemba. Passenger arrivals: Mafia Island. Percentage of upgrade complete: Mafia Island. Percent disbursed on construction works: Mafia Island.
Water Sector Project	$64,043,701	*Increase investment in human and physical capital and to reduce the prevalence of water-related disease.*	$23,940,404	Number of domestic customers (Dar es Salaam). Number of domestic customers (Morogoro). Number of non-domestic (commercial and institutional) customers(Dar es Salaam). Number of non-domestic (commercial and institutional) customers (Morogoro). Volume of water produced (Lower Ruvu). Volume of water produced (Morogoro). Percent disbursed on feasibility design update contract Lower Ruvu Plant Expansion.
Program Administration [2] and Control, Monitoring and Evaluation.	$55,749,222	.....	$22,171,696	
Pending Subsequent Report.[3]		.....	$99,857	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Burkina Faso Year: 2012 Quarter 1 Total Obligation: $480,943,569 Entity to which the assistance is provided: MCA Burkina Faso Total Quarterly Expenditures [1]: $15,135,359				
Roads Project	$194,130,681	*Enhance access to markets through investments in the road network.*	$6,386,017	*Annual average daily traffic: Dedougou-Nouna.* Annual average daily traffic: Nouna-Bomborukuy. Annual average daily traffic: Bomborukuy-Mali border. Kilometers of road under works contract. Kilometers of road under design/feasibility contract. Access time to the closest market via paved roads in the Sourou and Comoe (minutes). Kilometers of road under works contract. Kilometers of road under design/feasibility contract. Personnel trained in procurement, contract management and financial systems. Periodic road maintenance coverage rate (for all funds) (percentage).
Rural Land Governance Project.	$59,934,615	*Increase investment in land and rural productivity through improved land tenure security and land management.*	$14,435,605	Trend in incidence of conflict over land rights reported in the 17 pilot communes (Annual percentage rate of change in the occurrence of conflicts over land rights). Number of legal and regulatory reforms adopted. Number of stakeholders reached by public outreach efforts. Personnel trained. Number of Services Fonciers Ruraux (rural land service offices) installed and functioning. Rural hectares formalized. Number of parcels registered in Ganzourou project area.
Agriculture Development Project.	$141,910,059	*Expand the productive use of land in order to increase the volume and value of agricultural production in project zones.*	$22,139,683	New irrigated perimeters developed in Di (Hectares). Technical water management core teams (noyaux techniques) installed and operational in the two basins (Sourou and Comoe). Number of farmers trained. Number of agro-sylvo-pastoral groups which receive technical assistance. Number of loans provided by the rural finance facility. Volume of loans intended for agro-sylvo-pastoral borrowers (million CFA).
Bright II Schools Project ...	$28,829,669	*Increase primary school completion rates.*	$28,537,947	Number of girls/boys graduating from BRIGHT II primary schools. Percent of girls regularly attending (90% attendance) BRIGHT schools. Number of girls enrolled in the MCC/USAID-supported BRIGHT schools. Number of additional classrooms constructed. Number of teachers trained through 10 provincial workshops.
Program Administration [2] and Control, Monitoring and Evaluation.	$56,138,545	.....	$24,328,478	
Pending Subsequent Report.[3]		.....	$0	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Namibia Year: 2012 Quarter 1 Total Obligation: $304,376,121 Entity to which the assistance is provided: MCA Namibia Total Quarterly Expenditures [1]: $15,866,924				
Education Project	$144,976,555	*Improve the quality of the workforce in Namibia by enhancing the equity and effectiveness of basic.*	$29,695,174	Percentage of students who are new entrants in grade 5 for 47 schools. Percent of contracted construction works disbursed for 47 schools. Percent disbursed against design/supervisory contracts for 47 schools. Percentage of schools with a learner-textbook ration of 1 to 1 in science, math, and English. Number of textbooks delivered. Number of teachers and managers trained in textbook management, utilization, and storage. Percent disbursed against works contracts for Regional Study Resource Centers Activity (RSRCS). Percent disbursed against design/supervisory contracts for RSRCs. Number of vocational trainees enrolled through the MCA–N grant facility. Value of vocational training grants awarded through the MCA–N grant facility. Percent disbursed against construction, rehabilitation, and equipment contracts for Community Skills and Development Centres (COSDECS). Percent disbursed against design/supervisory contracts for COSDECS.
Tourism Project	$66,994,938	*Grow the Namibian tourism industry with a focus on increasing income to households in communal.*	$10,757,023	Percent of condition precedents and performance targets met for Etosha National Park (ENP) activity. Number of game translocated with MCA–N support. Number of unique visits on Namibia Tourism Board (NTB) website. Number of North American tourism businesses (travel agencies and tour operators) that offer Namibian tours or tour packages. Value of grants issued by the conservancy grant fund (Namibian dollars). Amount of private sector investment secured by MCA–N assisted conservancies (Namibian dollars). Number of annual general meetings with financial reports submitted and benefit distribution plans discussed.
Agriculture Project	$47,550,008	*Enhance the health and marketing efficiency of livestock in the NCAs of Namibia and to increase income.*	$14,812,385	Number of participating households registered in the Community-based Rangeland and Livestock Management (CBRLM) sub-activity. Number of grazing area management implementation agreements established under CBRLM sub-activity. Number of community land board members and traditional authority members trained. Number of cattle tagged with radio frequency identification (RFID) tags. Percent disbursed against works contracts for State Veterinary Offices. Percent disbursed against design/supervisory contracts for State Veterinary Offices. Value of grant agreements signed under Livestock Market Efficiency Fund. Number of Indigenous Natural Product (INP) producers selected and mobilized. Value of grant agreements signed under INP Innovation Fund.
Program Administration [2] and Control, Monitoring and Evaluation.	$44,904,620	.....	$14,832,891	
Pending Subsequent Report.[3]		.....	$5,836,568	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Moldova Year: 2012 Quarter 1 Total Obligation: $262,000,000 Entity to which the assistance is provided: MCA Moldova Total Quarterly Expenditures [1]: $1,099,282				
Road Rehabilitation Project	$132,840,000	*Enhance transportation conditions.*	$463,562	Reduced cost for road users. Average annual daily traffic. Road maintenance expenditure. Kilometers of roads completed. Percent of contracted roads works disbursed. Kilometers of roads under works contracts. Resettlement Action Plan (RAP) implemented. Final design. Kilometers of roads under design.
Transition to High Value Agriculture Project.	$101,773,402	*Increase incomes in the agricultural sector; Create models for transition to HVA in CIS areas and an enabling environment (legal, financial and market) for replication.*	$6,252,810	Hectares under improved or new irrigation. Centralized irrigation systems rehabilitated. Percent of contracted irrigation feasibility and/or design studies disbursed. Value of irrigation feasibility and/or detailed design contracts signed. Water user associations (WUA) achieving financial sustainability. WUA established under new law. Revised water management policy framework—with long-term water rights defined—established. Contracts of association signed. Irrigation Sector Reform (ISRA) Contractor mobilized. Additionally factor of Access to Agricultural Finance (AAF) investments. Value of agricultural and rural loans. Number of all loans. Number of all loans (female). High value agriculture (HVA) Post-Harvest Credit Facility launched HVA Post-Harvest Credit Facility Policies and Procedures Manual (PPM) Finalized. Number of farmers that have applied improved techniques (Growing High Value Agriculture Sales [GSH]). Number of farmers that have applied improved techniques (GHS) (female). Number of farmers trained. Number of farmers trained (female). Number of enterprises assisted. Number of enterprises assisted (female). GHS activity launched.
Program Administration [2] and Monitoring and Evaluation.	$27,386,598	.....	$2,564,135	
Pending Subsequent Report.[3]		.....	$6,506	

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Philippines Year: 2012 Quarter 1 Total Obligation: $432,829,526 Entity to which the assistance is provided: MCA Philippines Total Quarterly Expenditures [1]: $2,372,537				
Kalahi-CIDSS Project	$120,000,000	*Improve the responsiveness of local governments to community needs, encourage communities to engage in development activities.*	$4,530,766	Percentage of Municipal Local Government Units (MLGUs) that provide funding support for KC sub-project operations and maintenance. Number of completed KC sub-projects implemented in compliance with technical plans and within schedule and budget. Percentage of communities with KC sub-projects that have sustainability evaluation rating of satisfactory or better.
Secondary National Roads Development Project.	$213,412,526	*Reduce transportation costs and improve access to markets and social services.*	$5,023,893	Motorized traffic time cost. Kilometers of road sections completed. Value of road construction contracts disbursed. Value of signed road feasibility and design contracts. Value of road feasibility and design contracts disbursed.

Projects	Obligated	Objectives	Cumulative expenditures	Measures
Revenue Administration Reform Project.	$54,300,000	*Increase tax revenues over time and support the Department of Finance's initiatives to detect and deter corruption within its revenue agencies.*	$228,038	Number of audits performed. Number of Revenue District Offices using the electronic tax information system (eTIS). Number of successful case resolutions.
Program Administration [2] and Control, Monitoring and Evaluation.	$45,117,000	.....	$1,468,884	
Pending Subsequent Reports.[3]		.....	$3,140,918	
Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Senegal Year: 2012 Quarter 1 Total Obligation: $540,000,000 Entity to which the assistance is provided: MCA Senegal Total Quarterly Expenditures [1]: $1,229,343				
Road Rehabilitation Project	$324,712,499	*Expand Access to Markets and Services.*	$2,079,096	Tons of irrigated rice production. Kilometers of roads rehabilitated on the RN#2. Annual average daily traffic Richard-Toll—Ndioum. Percentage change in travel time on the RN # 2. International Roughness Index on the RN#2 (Lower number = smoother road). Kilometers (km) of roads covered by the contract for the studies, the supervision and management of the RN#2. Kilometers of roads rehabilitated on the RN#6. Annual average daily traffic Ziguinchor—Tanaff. Annual average daily traffic Tanaff—Kolda. Annual average daily traffic Kolda—Kounkané. Percentage change in travel time on the RN # 6. International Roughness Index on the RN#6 (Lower number = smoother road). Kilometers (km) of roads covered by the contract for the studies, the supervision and management of the RN#6.
Irrigation and Water Resources Management Project.	$170,008,860	*Improve productivity of the agricultural sector.*	$287,228	Tons of irrigated rice production. Potentially irrigable lands area (Delta and Ngallenka). Hectares under production. Total value of feasibility, design and environmental study contracts signed for the Delta and the Ngallenka (including RAPs). Cropping intensity (hectares under production per year/cultivable hectares). Number of hectares mapped to clarify boundaries and land use types. Percent of new conflicts resolved. Number of people trained on land security tools.
Program Administration [2] and Monitoring and Evaluation.	$45,278,641	.....	$5,505,351	
Pending Subsequent Report.[3]		.....	$430,785	
Projects	Obligated	Objectives	Cumulative expenditures	Measures
Country: Jordan Year: 2012 Quarter 1 Total Obligation: $275,100,000 Entity to which the assistance is provided: MCA Senegal Total Quarterly Expenditures: $ − 1,316,454				
Water Network Restructuring and Rehabilitation.	$102,570,034	TBD		TBD
Wastewater Collection	$58,224,386	TBD		TBD
Expansion of Wastewater Treatment Capacity.	$93,025,488	TBD		TBD
Program Administration [2] and Monitoring and Evaluation.	$21,280,092	.....	$43,116	
Pending Subsequent Report.[3]				

The negative expense relates to expense accruals and disbursements for the quarter.

[1] Expenditures are the sum of cash outlays and quarterly accruals for work in process and invoices received but not yet paid.

[2] Program administration funds are used to pay items such as salaries, rent, and the cost of office equipment.
[3] These amounts represent disbursements made that will be allocated to individual projects in the subsequent quarter(s) and reported as such in subsequent quarterly report(s).

619(B) TRANSFER OR ALLOCATION OF FUNDS

U.S. Agency to which Funds were Transferred or Allocated	Amount	Description of program or project
None	None	None

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NATIONAL SCIENCE FOUNDATION

Call for Papers: National Symposium on Moving Target Research

AGENCY: The National Coordination Office (NCO) for Networking and Information Technology Research and Development (NITRD).

ACTION: Call for Papers (CFP).

FOR FURTHER INFORMATION, CONTACT: *mtr-symposium@sei.cmu.edu.*

DATES: To be considered, draft papers must be received by 18:00 EDT, April 2, 2012.

SUMMARY: This Call for Papers is being issued by the National Coordination Office for the Networking and Information Technology Research and Development (NITRD) Program to initiate the National Symposium on Moving Target Research. The Symposium intends to bring together and publish the work of the Moving Target cybersecurity research community to provide a basis for building on the current state of the art.

SUPPLEMENTARY INFORMATION:

Background: In December 2011, the White House, in cooperation with the Networking and Information Technology Research and Development (NITRD) Program released the NSTC report ''Trustworthy Cyberspace: Strategic Plan for the Federal Cybersecurity Research and Development Program.'' One of the research themes outlined in this plan was Moving Target (MT), research and development that results in the presentation of a dynamic attack surface to an adversary, increasing the work factor necessary to successfully attack and exploit a cyber target. Throughout the federal government, research related to MT has been funded since 2009, but there is no single venue where this work is presented and published. The Symposium on Moving Target Research intends to bring together and publish the work of the MT community to provide a basis for building on the current state of the art.

Location: This Symposium will take place at the Historic Inns of Annapolis, Annapolis, MD on June 11, 2012. A registration site will be announced in April 2012 for attendees. A limited block of rooms will be available at the Historic Inns of Annapolis at the U.S. Government rate for June 10–13, 2012.

Objective: The central question of the symposium will be ''is there scientific evidence to show that moving target techniques are a substantial improvement in the defense of cyber systems (a game changer),'' including how to develop better measures of effectiveness and performance specific to moving target techniques. MT topics of interest include, but are not restricted to:

- Dynamic network services
- Game theoretic approaches
- Virtual machines
- Cloud computing
- Dynamic execution
- Automated response actions
- Situational awareness
- MT transparency
- Work factor metrics
- Risk analysis
- End-to-end security
- Resiliency
- Intrusion Tolerance
- Measures of effectiveness

Submission: Submitted papers must be 7–12 pages in 11 point font including figures and references. Appendences no longer than 8 pages may be submitted in addition to the paper, but the paper must be intelligible without these appendences. Submitted papers must not substantially overlap with papers that have been published or that are simultaneously submitted to a journal or conference proceedings. Papers will be subject to peer-review and selection based on technical rigor, application of scientific method, and contribution to the overall area of moving target. There will be an accompanying poster session open for researchers and companies that would like to highlight or demonstrate available MT technologies. Papers should be emailed in pdf format to (*mtr-symposium@sei.cmu.edu*) by 18:00 EDT, April 2, 2012 for consideration. You may also use this email address for any questions you have concerning this upcoming event.

Important Dates (all due dates/time 18:00 EDT):

Draft Papers due April 2, 2012
Notification April 20, 2012
Poster abstracts due May 4, 2012
Camera-ready copy due May 18, 2012
Symposium June 11, 2012, Annapolis, MD

Program Committee:

Matt Bishop, UC Davis
Deb Frincke, NSA
Matt Gaston, CMU
Sushil Jajodia, GMU
Tom Longstaff, NSA
Ed Rhyne, DHS
Bill Scherlis, CMU
Cliff Wang, ARO
Jeannette Wing, CMU

Submitted by the National Science Foundation for the National Coordination Office (NCO) for Networking and Information Technology Research and Development (NITRD) on March 1, 2012.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2012–5481 Filed 3–6–12; 8:45 am]
BILLING CODE 7555–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Proposed Information Collection; Comment Request

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), on November 1, 2011 (76 FR 67496), the Occupational Safety and Health Review Commission (OSHRC) published a 60-day notice in the **Federal Register** soliciting public comment on the proposed information collection described below.

In further compliance with the PRA, OSHRC now publishes this second notice announcing the submission of its proposed collection to the Office of Management and Budget (OMB) for

review and notifying the public about how to submit comments on the proposed collection to OMB during the 30-day comment period.

DATES: Comments must be submitted to OMB on or before April 6, 2012.

ADDRESSES: Submit all comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Occupational Safety and Health Review Commission, Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: (202) 395–6929/Fax: (202) 395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for information or copies of the proposed information collection instrument should be directed to John X. Cerveny, Deputy Executive Secretary, Occupational Safety and Health Review Commission, 1120 20th Street NW., Ninth Floor, Washington, DC 20036–3457; Telephone (202) 606–5706; email address: *pracomments@oshrc.gov.*

SUPPLEMENTARY INFORMATION: OSHRC's Settlement Part program, codified at 29 CFR 2200.120, is designed to encourage settlements on contested citations issued by the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) and to reduce litigation costs. The program requires employers who receive job safety or health citations that include proposed penalties of $100,000 or more in total to participate in formal settlement talks presided over by an OSHRC Administrative Law Judge. If settlement efforts fail, the case would continue under OSHRC's conventional proceedings, usually before a judge other than the one who presided over the settlement proceedings.

To ensure the continued success of the program, OSHRC proposes to collect information from Settlement Part participants about their experiences with the program. The participants would be employers and Department of Labor personnel, Authorized Employee Representatives and their representatives, including attorneys, who have personally participated in cases from February 15, 2011 through February 14, 2012. The proposed information collection instrument is a written survey consisting of a series of multiple-choice questions that are intended to take a respondent no more than 30 minutes to complete. The respondents may skip any questions that they do not feel comfortable answering, and are permitted to comment further on their experiences at the end of the questionnaire.

OSHRC has submitted the proposed information collection to OMB for review, as required by the PRA. OSHRC invites comments to be submitted to OMB on: (1) Whether the proposed collection of information is necessary for the proper performance of the agency's functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

OMB Control Number: Not applicable, new request.

Form Number: Not applicable.

Type of Review: Regular submission (new information collection).

Title: Survey of Participants in OSHRC Settlement Part Program.

Description: Information collection required to evaluate the Review Commission's Settlement Part process.

Affected Public: Employer and Department of Labor (OSHA) personnel (settlement decision makers), Authorized Employee Representatives, and their representatives, including attorneys, who have personally participated in cases subject to Mandatory and Voluntary Settlement proceedings under 29 CFR 2200.120 from February 15, 2011 through February 14, 2012.

Estimated Number of Respondents: 300.

Estimated Time per Response: 30 minutes.

Estimated Total Reporting Burden: 150 hours.

Obligation to respond: Voluntary.

Dated: March 2, 2012.

Debra Hall,

Acting Executive Director.

[FR Doc. 2012–5546 Filed 3–6–12; 8:45 am]

BILLING CODE 7600–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29973; 812–13493]

American Capital, Ltd., et al.; Notice of Application

March 1, 2012.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under section 6(c) of the Investment Company Act of 1940 (the ''1940 Act'') granting an exemption from section 12(d)(3) of the 1940 Act.

Applicants: American Capital, Ltd. (the ''Company''), American Capital, LLC (''AC LLC''), American Capital Mortgage Management, LLC (''ACMM''), and European Capital Financial Services (Guernsey) Limited (''ECFSG'').

SUMMARY: *Summary of Application:* The Company, AC LLC, ACMM, and ECFSG (collectively, the ''Applicants'') request an order (''Order'') of the Commission pursuant to section 6(c) of the 1940 Act granting an exemption from the provisions of section 12(d)(3) of the 1940 Act, to the extent necessary at such time as AC LLC and the AC Subs (as defined below) are required to become registered investment advisers under the Investment Advisers Act of 1940 (the ''Advisers Act''), in order to allow: the Company to continue to hold up to 100% of the outstanding membership interests of AC LLC; AC LLC to continue to hold up to 100% of the outstanding membership interests of the AC Subs and ACMM; ACMM to continue to hold up to 100% of the outstanding membership interests of American Capital AGNC Management, LLC (''AC Agency'') and American Capital MTGE Management, LLC (''AC Mtge''); and ECFSG to continue to hold up to 100% of the outstanding membership interests of European Capital Financial Services Limited (''ECFS'').

DATES: *Filing Dates:* The application was filed on February 12, 2008, and amended on March 11, 2011, November 23, 2011, February 22, 2012, and February 29, 2012.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on March 26, 2012, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE.,

Washington, DC 20549–1090. Applicants, 2 Bethesda Metro Center, 14th Floor, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Jill Ehrlich, Senior Counsel, at (202) 551–6819, or David P. Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

Applicants' Representations

1. The Company, incorporated in Delaware in 1986, is a non-diversified, closed-end investment company that has elected to be regulated as a business development company (''BDC'') within the meaning of section 2(a)(48) under the 1940 Act.[1] The Company's primary business objectives are to increase its net operating income and net asset value by investing primarily in senior debt, subordinated debt and equity of middle market businesses with attractive current yields and potential for equity appreciation and realized gains. Most of the Company's investments are made in connection with buyout transactions, which are sponsored either by the Company or another entity. The Company also makes investments in certain structured financial products and alternative asset funds managed by AC LLC, as well as certain portfolio companies in which the Funds (as defined below) also are investors.

2. The Company is internally managed with an eight-member board and a senior management staff consisting of eight executive officers (one of whom also is a director). Seven of the eight current members of the board are not ''interested persons'' of the Company as defined in section 2(a)(19) of the 1940 Act. In addition to approving investment decisions, the Company's directors are actively involved in the oversight of the Company's affairs, and the Company relies extensively on the judgment and experience of its directors.

3. The Company's alternative asset fund management business is conducted through AC LLC, a Delaware limited liability company that was created in 2007 and is a wholly-owned subsidiary of the Company. AC LLC currently manages a number of private investment funds and two public real estate investment trusts (collectively, the ''Funds'') through the following direct and indirect subsidiaries (collectively, the ''AC Subs''): American Capital Equity Management, LLC (''ACEM''); American Capital Equity Management II, LLC (''ACEM2''); American Capital Asset Management, LLC (''ACAM''); American Capital CRE Management, LLC (''ACREM''); AC Agency; AC Mtge; ECFSG; and ECFS.

4. ACEM, ACEM2, ACAM, ACREM, and ECFSG are each wholly-owned by AC LLC. ECFS is wholly-owned by ECFSG. AC Agency and AC Mtge are wholly-owned subsidiaries of ACMM. ACMM is owned by AC LLC, with one employee of ACMM owning a less than 25% economic (non-voting) interest, and AC LLC owning a 100% voting interest. The Company, AC LLC, and the AC Subs utilize certain overlapping personnel, as described in the application.

5. The AC Subs generally earn base management fees based on the gross assets or net asset value of the Funds they manage, and certain of them earn incentive income based on the performance of the Funds. ACREM earns collateral administration fees based on the collateral balance in the Fund it manages.

6. AC LLC and the AC Subs currently rely on the registration exemption set forth in section 203(b)(3) of the Advisers Act, which provides generally that an investment adviser with fewer than 15 clients is not required to register with the Commission. However, the Dodd-Frank Wall Street Reform and Consumer Protection Act[2] eliminated this exemption, and AC LLC and the AC Subs will, based on their assets under management, be required to register with the Commission.[3]

Applicants' Legal Analysis

1. Section 12(d)(3) makes it unlawful for any registered investment company, and any company controlled by a registered investment company, to acquire any interest in the business of a person who is either an investment adviser of an investment company or an investment adviser registered under the Advisers Act, unless (a) such person is a corporation all the outstanding securities of which are owned by one or more registered investment companies; and (b) such person is primarily engaged in the business of underwriting and distributing securities issued by other persons, selling securities issued by other persons, selling securities to customers, or any one or more of such or related activities, and the gross income of such person normally is derived principally from such business or related activities. Section 60 of the 1940 Act states that section 12 shall apply to a BDC to the same extent as if it were a registered closed-end investment company.

2. Section 6(c) of the 1940 Act provides that the Commission may conditionally or unconditionally exempt any person, security or transaction from any provision of the 1940 Act or any rule thereunder if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

3. Applicants do not expect that AC LLC and the AC Subs would be broker-dealers that primarily engage in the business of underwriting and distributing securities issued by other persons. Accordingly, provided that the ''related activities'' phrase of section 12(d)(3)(B) is not interpreted to include investment advisory services, when it becomes necessary for AC LLC and the AC Subs to register as investment advisers, the Company's current ownership of AC LLC and the AC Subs could cause the Company to be in violation of the provisions of section 12(d)(3).[4] Therefore, Applicants request the Order pursuant to section 6(c) of the 1940 Act granting an exemption from the provisions of section 12(d)(3) of the 1940 Act, to the extent necessary at such

[1] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the 1940 Act, makes available significant managerial assistance with respect to the issuers of such securities, and has elected to be subject to the provisions of sections 55 through 65 of the 1940 Act.

[2] Private Fund Investment Advisers Registration Act of 2010, Title IV of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Neither AC LLC nor any of the AC Subs qualify for any exemption from registration available under rules recently adopted by the Commission. *Exemptions for Advisers to Venture Capital Funds, Private Fund Advisers With Less Than $150 Million in Assets Under Management, and Foreign Private Advisers,* Release No. IA–3222 (June 22, 2011) (adopting release).

[3] *Rules Implementing Amendments to the Investment Advisers Act of 1940,* SEC Release No. IA–3221 (July 22, 2011). AC LLC and the AC Subs will be registered as investment advisers under the Advisers Act, and the Company will not acquire any interest in an investment adviser that is not registered under the Advisers Act.

[4] Rule 12d3–1 under the 1940 Act provides limited relief from the restrictions of section 12(d)(3). Applicants do not believe the Company may rely on this relief with respect to its investment in AC LLC or the AC Subs because AC LLC's and the AC Subs' gross revenues derived from securities-related activities will exceed the rule's quantitative limits for such revenues.

time as AC LLC and the AC Subs are required to become registered investment advisers, in order to allow: the Company to continue to hold up to 100% of the outstanding membership interests of AC LLC; AC LLC to continue to hold up to 100% of the outstanding membership interests of the AC Subs and ACMM; ACMM to continue to hold up to 100% of the outstanding membership interests of AC Agency and AC Mtge; and ECFSG to continue to hold up to 100% of the outstanding membership interests of ECFS.[5]

4. Applicants state that section 12(d)(3) was intended (a) to prevent investment companies from exposing their assets to the entrepreneurial risks of securities-related businesses and (b) to prevent potential conflicts of interest and certain reciprocal practices between investment companies and securities-related businesses.

5. Applicants submit that the Company's retention of its majority ownership of AC LLC and the AC Subs does not raise the issues regarding entrepreneurial risk that section 12(d)(3) was designed to prevent. Applicants state that the form of organization of many securities-related businesses has changed since 1940, when section 12(d)(3) was adopted, from general partnerships to structures that are characterized by limited liability. Applicants assert that AC LLC and the AC Subs do not expose the Company's stockholders to the risk of unlimited liability because each is organized as a separate entity whose owners have limited liability.

6. Applicants also submit that the Company's retention of its majority ownership of AC LLC and the AC Subs does not raise the issues regarding conflicts of interest and reciprocal practices that section 12(d)(3) was designed to prevent. Because the Company is the sole owner of AC LLC and the sole or majority owner of each AC Sub and will maintain a majority voting interest and economic interest in AC LLC and each of the AC Subs, Applicants believe that ultimately the interests of the companies are generally aligned and that the likelihood of conflicts of interest arising is low. Applicants also assert that there are generally no investment allocation conflicts between the Company and the Funds.[6] Applicants represent that the procedures and policies that the Company has adopted with respect to AC LLC and the AC Subs and the methods of operations proposed will ensure that the Company will continue to be operated and managed in the interests of its stockholders and that ownership by it of AC LLC and the AC Subs will otherwise be consistent with the purposes fairly intended by the policy and provisions of the 1940 Act. Applicants also represent that, at such time as AC LLC and the AC Subs are required to register as investment advisers under the Advisers Act, they will maintain formal policies and procedures related to their operations (including appointing a chief compliance officer) that are designed to ensure that management of AC LLC and the AC Subs is conducted in the best interests of the Funds, as well as their shareholders.[7]

7. Applicants further submit that the conditions to the requested relief proposed in the Application will protect the Company from potential conflicts of interest and reciprocal practices by making it impossible for the Company to become a minority owner of AC LLC or any AC Sub, and the Company's board of directors will periodically review whether continued ownership of the advisory businesses is warranted. In addition, Applicants assert that the 1940 Act would not prevent the Company from engaging directly in the activities that it conducts through AC LLC and the AC Subs.

8. Applicants state that registering AC LLC and the AC Subs as investment advisers and maintaining a majority of both their voting rights and economic interests, will enable the Company to continue to increase its earnings potential through AC LLC's existing advisory business, as well as other potential advisory business, and maintain and, ultimately, increase the profitability of the Company. Applicants also state that the organizational structure of the Company and its investment management affiliates could assist the Company in qualifying as a ''regulated investment company'' (''RIC'') under Subchapter M of the Internal Revenue Code of 1986.[8]

9. Applicants represent that the Company's management and its board believe that ensuring the ability to continue to own and invest in AC LLC is in the best interests of the Company's stockholders and its business. Applicants state that requiring the Company to divest itself of AC LLC and the AC Subs would cause substantial economic harm to the Company and, thus, the Company's stockholders.

10. Accordingly, Applicants represent that the requested relief is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

Applicants' Conditions

Applicants agree that the Order of the Commission granting the requested relief shall be subject to the following conditions:

1. The Company will not dispose of the interests of AC LLC or an AC Sub if, as a result, the Company would own, directly or indirectly, 50 percent or less of the outstanding voting interests or economic interests of AC LLC or the AC Sub unless the Company disposes of 100 percent of its membership interests in AC LLC or the AC Sub.

2. The board of directors of the Company will review at least annually the investment management business of the Company, AC LLC and the AC Subs in order to determine whether the benefits derived by the Company warrant the continuation of the ownership by the Company of AC LLC and the AC Subs and, if appropriate, will approve (by at least a majority of the directors of the Company who are not ''interested persons'' of the Company as defined by the 1940 Act) at least annually, such continuation.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–5514 Filed 3–6–12; 8:45 am]

BILLING CODE 8011–01–P

[5] The Company will only rely on the Order with respect to its investments in AC LLC and the AC Subs, AC LLC will only rely on the Order with respect to the AC Subs, ACMM will only rely on the Order with respect to AC Agency and AC Mtge, and ECFSG will only rely on the Order with respect to ECFS.

[6] Applicants nevertheless state that they are focused on ensuring that any potential conflicts of interest are identified and addressed. Among other things, Applicants represent that, although the Company, AC LLC, and the AC Subs utilize overlapping personnel, their legal and compliance teams would generally implement procedures to restrict communications between investment professionals should a conflict arise. Applicants also represent that each maintains investment committees that follow consistent processes for investment decisions and vote separately on behalf of each fund. Applicants believe this structure facilitates the detection and avoidance of potential conflicts of interest throughout the investment process, as well as during the time a portfolio investment is held.

[7] Applicants also assert that the Company's ownership of AC LLC and the AC Subs does not raise concerns of ''propping'' because the Company is not dependent on AC LLC or any AC Sub either for revenue or investment advice and because the advisory subsidiaries will not issue any public securities to ''prop up.''

[8] Taxation as a RIC relieves the Company of federal income tax on its net investment income and net realized capital gains, if any, to the extent that they are distributed to stockholders.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29974; 812–13879]

Fidus Investment Corporation, et al.; Notice of Application

March 1, 2012.

AGENCY: Securities and Exchange Commission (the ''Commission'').

ACTION: Notice of an application for an order under sections 6(c), 12(d)(1)(J), and 57(c) of the Investment Company Act of 1940 (''Act'') granting exemptions from sections 12(d)(1)(A), 18(a), 21(b), 57(a)(1)–(a)(3), and 61(a) of the Act; under section 57(i) of the Act and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by section 57(a)(4) of the Act; and under section 12(h) of the Securities Exchange Act of 1934 (''Exchange Act'') granting an exemption from section 13(a) of the Exchange Act.

APPLICANTS: Fidus Investment Corporation (''Company''), Fidus Mezzanine Capital, L.P. (''Fidus SBIC''), Fidus Investment GP, LLC (''New General Partner''), and Fidus Investment Advisors, LLC (''Fidus Advisors'').

SUMMARY OF APPLICATION: Applicants request an order permitting the Company, a business development company (''BDC'') and Fidus SBIC, its wholly-owned small business investment company (''SBIC'') subsidiary that is also a BDC, to operate effectively as one company, specifically allowing them to (1) engage in certain transactions with each other; (2) invest in securities in which the other is or proposes to be an investor; (3) be subject to modified asset coverage requirement for senior securities issued by a BDC and its SBIC subsidiary; and (4) file certain reports with the Commission on a consolidated basis.

DATES: *Filing Dates:* The application was filed on March 15, 2011, and amended on August 9, 2011, and February 28, 2012.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5.30 p.m. on March 26, 2012, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, c/o Edward H. Ross, Fidus Investment Corporation, 1603 Orrington Avenue, Suite 820, Evanston, Illinois 60201.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551–6990, or Jennifer L. Sawin, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Company, a Maryland corporation, is an externally-managed, non-diversified, closed-end management investment company that has elected to be regulated as a BDC under the Act.[1] On June 16, 2011, the Company filed a registration statement to register its common stock under Section 12 of the Exchange Act.[2] In addition, the Company intends to elect to be treated as a regulated investment company (''RIC'') as defined under Subchapter M of the Internal Revenue Code of 1986, as amended and intends to continue to make such election in the future. The Company provides customized mezzanine debt and equity financing solutions to lower middle market companies that have revenues between $10 and $150 million. The Company's board of directors (''Board''), consists of five members, three of whom are not ''interested persons'' of the Company within the meaning of section 2(a)(19) of the Act. The Company's investment objective is to provide attractive risk-adjusted returns by generating both current income from debt investments and capital appreciation from equity related investments.

2. Fidus SBIC, a Delaware limited partnership, is an SBIC licensed by the Small Business Administration (''SBA'') to operate under the Small Business Investment Act of 1958. On June 20, 2011, Fidus SBIC filed an election to be regulated as a BDC within the meaning of Section 2(a)(48) on Form N–54A under the Act in connection with the effectiveness of its registration statement on Form N–5. On June 16, 2011, Fidus SBIC also filed a registration statement on Form 8–A to register its common stock under Section 12 of the Exchange Act. Fidus SBIC has the same investment objectives and strategies as the Company. The Company owns a 99.99% limited partnership interest in Fidus SBIC; the New General Partner, a wholly-owned subsidiary of the Company, owns a 0.01% general partnership interest in Fidus SBIC. Fidus SBIC, therefore, is a wholly-owned subsidiary of the Company, because the Company and the New General Partner own all of the partnership and voting interests in Fidus SBIC. Fidus SBIC is and will remain, at all times, a wholly-owned subsidiary of the Company and consolidated with the Company for financial reporting purposes. Fidus SBIC has a board of directors (''Fidus SBIC Board'') consisting of three persons who are not ''interested persons'' of Fidus SBIC within the meaning of section 2(a)(19) of the Act and two persons who are ''interested persons'' of Fidus SBIC. The members of Fidus SBIC Board are appointed each year by the equity owners of Fidus SBIC. The New General Partner has irrevocably delegated the authority to manage the business affairs of Fidus SBIC to the Fidus SBIC Board. The SBA has approved the members of the Fidus SBIC Board pursuant to SBA regulations. No person who is not also a member of the Board of the Company can serve as a member of the Fidus SBIC Board.

3. Fidus Advisors is a Delaware limited liability company and serves as the investment adviser to the Company and Fidus SBIC. Fidus Advisors is registered as an investment adviser under the Investment Advisers Act of 1940. Pursuant to an investment management agreement with the Company that satisfies the requirements

[1] Section 2(a)(48) of the Act defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[2] The Company completed the initial public offering (''IPO'') of its shares of common stock on June 24, 2011. The Company's common stock is traded on the NASDAQ Global Market under the symbol ''FDUS''. Prior to the closing of the IPO, through a series of transactions (''Formation Transactions''), the Company acquired all of the limited partnership interests in Fidus SBIC and all of the membership interests in the New General Partner, and each of these entities operates as a subsidiary of the Company.

under Sections 15(a) and (c), Fidus Advisors manages the consolidated assets of the Company and Fidus SBIC. The investment professionals of Fidus Advisors are responsible for sourcing potential investments, conducting research and diligence on potential investments and equity sponsors, analyzing investment opportunities, structuring investments and monitoring the investments and portfolio companies of the Company and its wholly-owned subsidiaries, including Fidus SBIC.

4. The New General Partner is a limited liability company organized under the laws of the state of Delaware. The New General Partner is the sole general partner of Fidus SBIC and its only role is to perform ministerial functions that result from decisions made by Fidus Advisors; the New General Partner is not able to prevent Fidus Advisors from acting independently.

Applicants' Legal Analysis

1. Applicants request an order under sections 6(c), 12(d)(1)(J), 57(c) and 57(i) of the Act and rule 17d–1 under the Act granting exemptions from sections 12(d)(1)(A), 18(a), 21(b), 57(a)(1), 57(a)(2), 57(a)(3), and 61(a) of the Act and permitting certain joint transactions otherwise prohibited by section 57(a)(4) of the Act to permit the Company and Fidus SBIC to operate effectively as one company, specifically to: (a) Engage in certain transactions with each other; (b) invest in securities in which the other is or proposes to be an investor; and (c) be subject to modified consolidated asset coverage requirements for senior securities issued by a BDC and its subsidiary SBIC. Applicants also request an order under section 12(h) of the Exchange Act for an exemption for Fidus SBIC from section 13(a) of the Exchange Act, so as to allow filing of consolidated reports with the Commission.

2. Section 12 of the Act is made applicable to BDCs by section 60 of the Act. Section 12(d)(1)(A) makes it unlawful for any registered investment company to purchase or otherwise acquire the securities of another investment company, except to the extent permitted by sections 12(d)(1)(A)(i), (ii) and (iii). Rule 60a–1 exempts the acquisition by a BDC of the securities of an SBIC that is operated as a wholly-owned subsidiary of the BDC from section 12(d)(1)(A) of the Act. Accordingly, since the Company has elected BDC status and since Fidus SBIC is, and will at all times be, operated as a wholly owned subsidiary of the Company, the transfer of assets from the Company to Fidus SBIC should be exempt from the provisions of section 12(d)(1)(A) by virtue of rule 60a–1. However, the provisions of section 12(d)(1) also apply to the activities of Fidus SBIC since Fidus SBIC has elected BDC status under the Act. Any loans or advances by Fidus SBIC to the Company might be deemed to violate section 12(d)(1)(A)(ii) or (iii) if the loans or advances are construed as purchases of the securities of the Company by Fidus SBIC.

3. Applicants request an exemption under section 12(d)(1)(J) from section 12(d)(1)(ii) and (iii) of the Act to permit the acquisition by Fidus SBIC of any securities of the Company representing indebtedness. Section 12(d)(1)(J) of the Act provides that the Commission may exempt persons or transactions from any provision of section 12(d)(1) if and to the extent such exception is consistent with the public interest and the protection of investors. Applicants state that the requested relief meets this standard because Fidus SBIC's wholly owned subsidiary status and consolidated financial reporting with the Company will both eliminate the possibility of overreaching and prevent confusion as to the financial status of the Company to the Company's stockholders, who are the investors that the Act is intended to protect.

4. Section 18(a) prohibits a registered closed-end investment company from issuing any class of senior security or selling any such security of which it is the issuer unless the company complies with the asset coverage requirements set forth in that section. Section 61(a) applies section 18 to a BDC to the same extent as if the BDC were a registered closed-end investment company, subject to certain exceptions. Section 18(k), however, provides an exemption from sections 18(a)(1)(A) and (B) (relating to senior securities representing indebtedness) for SBICs.

5. Applicants state that a question exists as to whether the Company must comply with the asset coverage requirements of section 18(a) on a consolidated basis because the Company may be an indirect issuer of senior securities with respect to Fidus SBIC indebtedness. To do so would mean that the Company would treat as its own all assets held directly by the Company and Fidus SBIC and would also treat as its own any liabilities of Fidus SBIC, including liabilities of Fidus SBIC with respect to senior securities as to which Fidus SBIC is exempt from the provisions of sections 18(a)(1)(A) and (B) by virtue of section 18(k). Accordingly, applicants request relief under section 6(c) of the Act from sections 18(a) and 61(a) of the Act to permit the Company to exclude from its consolidated asset coverage ratio any senior security representing indebtedness that is issued by Fidus SBIC.

6. Section 6(c) of the Act, in relevant part, permits the Commission to exempt any transaction or class of transactions from any provision of the Act if, and to the extent that, such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that, without the requested relief from sections 18(a) and 61(a), the ability of Fidus SBIC to obtain the kind of financing that would be available to the Company if it were to conduct the SBIC operations itself would be restricted. Applicants state that applying section 18(k) to the Company with respect to any senior security representing indebtedness that is issued by Fidus SBIC would not harm the public interest by exposing investors to risks of unconstrained leverage, because the SBA regulates the capital structure of Fidus SBIC.

7. Sections 57(a)(1) and (2) of the Act generally prohibit, with certain exceptions, sales or purchases of any security or other property between BDCs and certain of their affiliates as described in section 57(b) of the Act. Section 57(b) includes any person, directly or indirectly, who controls, is controlled by, or is under common control with the BDC. Applicants state that the Company is an affiliated person of Fidus SBIC by reason of its direct ownership of all of the limited partnership interests in Fidus SBIC and its indirect ownership of all the general partnership interests in Fidus SBIC through its 100% ownership of the New General Partner. Fidus SBIC is an affiliated person of the Company because it is deemed to be under the control of the Company. Accordingly, the Company and Fidus SBIC are related to each other in the manner set forth in section 57(b).

8. Applicants state that there may be circumstances when it is in the interests of the Company and its stockholders that Fidus SBIC invest in securities of an issuer that may be deemed to be a controlled portfolio affiliate of the Company or that the Company invest in securities of an issuer that may be deemed to be a controlled portfolio affiliate of Fidus SBIC. Applicants therefore request an exemption from sections 57(a)(1) and 57(a)(2) of the Act to permit any transaction solely between the Company and Fidus SBIC with

respect to the purchase or sale of securities or other property. Applicants also seek an exemption from the provisions 57(a)(1) and (2) to allow any transaction involving the Company and/or Fidus SBIC and portfolio affiliates of either or both of the Company and/or Fidus SBIC, but only to the extent that the transaction would not be prohibited if the Company and Fidus SBIC were one company.

9. Section 57(c) provides that the Commission will exempt a proposed transaction from the provisions of sections 57(a)(1), (2), and (3) of the Act if the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching of any person concerned, and the proposed transaction is consistent with the policy of the BDC concerned and the general purposes of the Act.

10. Applicants submit that the requested relief from sections 57(a)(1) and (2) meets this standard. Applicants represent that the proposed operations as one company will enhance the efficient operations of the Company and its wholly owned subsidiary, Fidus SBIC, and allow them to deal with portfolio companies as if the Company and Fidus SBIC were one company. Applicants contend that the terms of the proposed transactions are reasonable and fair and do not involve overreaching of the Company or its stockholders by any person, and that the requested order would permit the Company and Fidus SBIC to carry out more effectively their purposes and objectives of investing primarily in small business concerns. Applicants also state that since Fidus SBIC will be a wholly owned subsidiary of the Company and since no officers or directors of the Company or Fidus SBIC (or any controlling persons or other ''upstream affiliates'' of the Company) will have any prohibited financial interest in the transactions described, there can be no overreaching on the part of any persons and no harm to the public interest in transactions solely between the Company and Fidus SBIC. Finally, applicants note that the proposed transactions are consistent with the policy of the Company and Fidus SBIC as specified in filings with the Commission and reports to stockholders, as well as consistent with the policies and provisions of the Act.

11. Section 57(a)(3) of the Act makes it unlawful for certain affiliated persons of a BDC, and certain affiliated persons of those persons, set out in section 57(b) to borrow money or other property from such BDC or from any company controlled by the BDC, except as permitted by section 21(b) or section 62. Section 21(b) of the Act (made applicable to BDCs by section 62) provides that it shall be unlawful for a BDC to lend any money or property, directly or indirectly, to any person that controls or is under common control with the BDC, except to any company that owns all of the outstanding securities of the BDC other than directors' qualifying shares.

12. The Company is an affiliated person of Fidus SBIC by reason of its direct ownership of all of the limited partnership interests in Fidus SBIC and its indirect ownership of all of the general partnership interests in Fidus SBIC through its 100% ownership of the New General Partner. The Company does not directly own all of the outstanding securities of Fidus SBIC because the New General Partner holds a 0.01% general partnership interest in Fidus SBIC and Fidus SBIC has issued SBA guaranteed debentures and, in the future, may have other outstanding securities in the form of indebtedness. Fidus SBIC is an affiliated person of the Company because it is deemed to be under the control of the Company. Accordingly, the Company is related to Fidus SBIC in the manner set forth in section 57(b) and Fidus SBIC is related to the Company in the manner set forth in section 57(b).

13. Applicants state that there may be instances when it would be in the best interests of the Company and its stockholders for the Company to make loans to Fidus SBIC or for Fidus SBIC to make loans to the Company. Applicants note that, in the case of loans from Fidus SBIC to the Company, the loans would be prohibited by section 21(b) and section 57(a)(3) because the borrower controls the lender and the lender may have outstanding securities not owned by the borrower. Accordingly, applicants request an order under section 6(c) exempting from the provisions of section 21(b) the lending of money or other property by Fidus SBIC to the Company. Applicants argue that because these transactions are solely between the Company and Fidus SBIC, its wholly-owned subsidiary, they will have no substantive economic effect and there is be no basis for overreaching or harm to the public interest. Applicants also request an order under section 57(c) exempting from the provisions of section 57(a)(3) the borrowing of money or property by the Company from Fidus SBIC.[3] Applicants submit that the requested relief meets the standards of section 57(c).

14. Section 57(a)(4) of the Act generally prohibits joint transactions involving any BDC or a company it controls and certain persons related to the BDC as specified in section 57(b) of the Act, acting as principal in contravention of such rules and regulations as the Commission may prescribe for the purpose of limiting or preventing participation by the BDC or controlled company on a basis less advantageous than that of the other participant. Section 57(i) of the Act provides that rules and regulations under section 17(d) of the Act, such as rule 17d–1, will apply to transactions subject to section 57(a)(4) in the absence of rules under that section. The Commission has not adopted rules under section 57(a)(4) with respect to joint transactions and, accordingly, the standards set forth in rule 17d–1 govern applicants' request for relief. Rule 17d–1 under the Act (made applicable to BDCs by section 57(i)) prohibits affiliated persons of a registered investment company, or an affiliated person of such person, or, when applying rule 17d–1 to implement section 57(a)(4), a person related to a BDC in a manner described in Section 57(b), acting as principal, from participating in any joint transaction or arrangement in which the BDC or a company it controls is a participant, unless the Commission has issued an order authorizing the arrangement.

15. Applicants request relief under section 57(i) and rule 17d–1to permit any joint transaction that would otherwise be prohibited by section 57(a)(4) between the Company and Fidus SBIC with respect to any transaction involving investments by the Company or Fidus SBIC in portfolio companies in which either is or is proposed to become an investor, but only to the extent that the transaction would not be prohibited if Fidus SBIC (and all of its assets and liabilities) were deemed to be part of the Company, and not a separate company.

16. In determining whether to grant an order under section 57(i) and rule 17d–1, the Commission considers whether the participation of the BDC in the joint transaction is consistent with the provisions, policies, and purposes of the Act, and the extent to which such participation is on a basis different from or less advantageous than that of other participants. Applicants state that the proposed transactions are consistent with the policy and provisions of the

[3] Applicants state that they are not seeking relief from Section 57(a)(3) for loans from the Company to Fidus SBIC because under the existing control structure, no such relief is necessary.

Act and will enhance the interests of the Company's stockholders while retaining for them the important protections afforded by the Act. In addition, because the joint participants will conduct their operations as though they comprise one company, the participation of one will not be on a basis different from or less advantageous than the others. Accordingly, applicants submit that the standard for relief under section 57(i) and rule 17d–1 is satisfied.

17. Section 54 of the Act provides that a closed-end company may elect BDC treatment under the Act if the company has either a class of equity securities registered under section 12 of the Exchange Act or has filed a registration statement pursuant to section 12 of the Exchange Act for a class of its equity securities. Section 12(g) of the Exchange Act requires issuers with specified assets and a specified number of security holders to register under the Exchange Act. As a BDC, the Company has registered its common stock under section 12(b) of the Exchange Act. In order to elect BDC treatment under the Act, Fidus SBIC voluntarily registered its securities under the Exchange Act even though it is not required to do so by section 12(g) of the Exchange Act.

18. By filing a registration statement under section 12 of the Exchange Act, absent an exemption, Fidus SBIC would be required to make periodic filings with the Commission, even though Fidus SBIC will have only one equity holder. Section 13 of the Exchange Act is the primary section requiring such filings. Accordingly, applicants request an order under section 12(h) of the Exchange Act exempting Fidus SBIC from the reporting requirements of section 13(a) of the Exchange Act.

19. Section 12(h) of the Exchange Act provides that the Commission may exempt an issuer from section 13 of the Exchange Act if the Commission finds that by reason of the number of public investors, amount of trading interest in the securities, the nature and extent of the activities of the issuer, income or assets of the issuer, or otherwise, that such action is not inconsistent with the public interest or the protection of investors. Fidus SBIC has only one investor, which is itself a reporting company, and no public investors. There will be no trading in Fidus SBIC securities, so no public interest or investor protective purpose will be served by separate Fidus SBIC reporting. Further, applicants state that the nature and extent of Fidus SBIC's activities are such that its activities will be fully reported through consolidated reporting in accordance with normal accounting rules. Accordingly, applicants believe that the requested exemption meets the standards of section 12(h) of the Exchange Act.

Applicants' Conditions

Applicants agree that the requested order will be subject to the following conditions:

1. The Company will at all times own and hold, beneficially and of record, all of the outstanding limited partnership interests in Fidus SBIC and all of the outstanding membership interests in the New General Partner, or otherwise own and hold beneficially all of the outstanding voting securities and equity interests of Fidus SBIC.

2. Fidus SBIC will have investment policies not inconsistent with those of the Company, as set forth in the Company's registration statement.

3. No person shall serve as a member of the Fidus SBIC Board unless such person shall also be a member of the Company's Board. The Fidus SBIC Board will be appointed by the equity owners of Fidus SBIC.

4. The Company will not itself issue or sell any senior security and the Company will not cause or permit Fidus SBIC to issue or sell any senior security of which the Company or Fidus SBIC is the issuer except to the extent permitted by section 18 (as modified for BDCs by section 61); provided that immediately after the issuance or sale of any such senior security by either the Company or Fidus SBIC, the Company and Fidus SBIC on a consolidated basis, and the Company individually, shall have the asset coverage required by section 18(a) (as modified by section 61(a)). In determining whether the Company and Fidus SBIC on a consolidated basis have the asset coverage required by section 18, as modified by section 61(a), any senior securities representing indebtedness of Fidus SBIC shall not be considered senior securities, and for purposes of the definition of ''asset coverage'' in section 18(h), shall be treated as indebtedness not represented by senior securities.

5. The Company will acquire securities of Fidus SBIC representing indebtedness only if, in each case, the prior approval of the SBA has been obtained. In addition, the Company and Fidus SBIC will purchase and sell portfolio securities between themselves only if, in each case, the prior approval of the SBA has been obtained.

6. No person shall serve or act as investment adviser to Fidus SBIC unless the Board and the stockholders of the Company shall have taken such action with respect thereto that is required to be taken pursuant to the Act by the functional equivalent of the Fidus SBIC Board and the equity holders of Fidus SBIC.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66495/March 1, 2012]

Order Making Fiscal Year 2012 Mid-Year Adjustments to Transaction Fee Rates

I. Background

Section 31 of the Securities Exchange Act of 1934 (''Exchange Act'') requires each national securities exchange and national securities association to pay transaction fees to the Commission.[1] Specifically, Section 31(b) requires each national securities exchange to pay to the Commission fees based on the aggregate dollar amount of sales of certain securities transacted on the exchange.[2] Section 31(c) requires each national securities association to pay to the Commission fees based on the aggregate dollar amount of sales of certain securities transacted by or through any member of the association other than on an exchange.[3]

Section 31 of the Exchange Act requires the Commission to annually adjust the fee rates applicable under Sections 31(b) and (c) to a uniform adjusted rate, and in some circumstances, to also make a mid-year adjustment. The Dodd-Frank Act amendments to Section 31 of the Exchange Act establish a new method for annually adjusting the fee rates applicable under Sections 31(b) and (c) of the Exchange Act. Specifically, the Commission must now adjust the fee rates to a uniform adjusted rate that is reasonably likely to produce aggregate fee collections (including assessments on security futures transactions) equal to the regular appropriation to the Commission for the applicable fiscal year.[4] For fiscal year 2012, the regular

[1] 15 U.S.C. 78ee.

[2] 15 U.S.C. 78ee(b).

[3] 15 U.S.C. 78ee(c).

[4] *See* 15 U.S.C. 78ee(j)(1) (The Commission must adjust the rates under Sections 31(b) and (c) to a ''uniform adjusted rate that, when applied to the baseline estimate of the aggregate dollar amount of sales for such fiscal year, is reasonably likely to produce aggregate fee collections under [Section 31] (including assessments collected under [Section 31(d)]) that are equal to the regular appropriation

Continued

appropriation to the Commission is $1,321,000,000.[5] On January 20, 2012 the Commission issued an order under Section 31(j)(1) of the Exchange Act setting the fee rates applicable under Sections 31(b) and (c) for fiscal year 2012.[6]

II. Determination of the Need for a Mid-Year Adjustment in Fiscal 2012

Under Section 31(j)(2) of the Exchange Act, the Commission must make a mid-year adjustment to the fee rates under Sections 31(b) and (c) in fiscal year 2012 if it determines, based on the actual aggregate dollar volume of sales during the first five months of the fiscal year, that the baseline estimate $71,646,369,036,088 is reasonably likely to be 10% (or more) greater or less than the actual aggregate dollar volume of sales for fiscal year 2012.[7] To make this determination, the Commission must estimate the actual aggregate dollar volume of sales for fiscal year 2012.

Based on data provided by the national securities exchanges and the national securities association that are subject to Section 31,[8] the actual aggregate dollar volume of sales during the first four months of fiscal year 2012 was $21,401,568,899,359.[9] Using these data and a methodology for estimating the aggregate dollar amount of sales for the remainder of fiscal year 2012 (developed after consultation with the Congressional Budget Office and the OMB),[10] the Commission estimates that the aggregate dollar amount of sales for the remainder of fiscal year 2012 to be $42,485,082,013,879. Thus, the Commission estimates that the actual aggregate dollar volume of sales for all of fiscal year 2012 will be $63,886,650,913,238.

Because the baseline estimate of $71,646,369,036,088 is more than 10% greater than the $63,886,650,913,238 estimated actual aggregate dollar volume of sales for fiscal year 2012, Section 31(j)(2) of the Exchange Act requires the Commission to issue an order adjusting the fee rates under Sections 31(b) and (c).

III. Calculation of the Uniform Adjusted Rate

Section 31(j)(2) specifies the method for determining the mid-year adjustment for fiscal 2012. Specifically, the Commission must adjust the rates under Sections 31(b) and (c) to a ''uniform adjusted rate that, when applied to the revised estimate of the aggregate dollar amount of sales for the remainder of fiscal year 2012, is reasonably likely to produce aggregate fee collections under Section 31 (including fees collected during such 5-month period and assessments collected under Section 31(d)) that are equal to $1,321,000,000.'' [11] In other words, the uniform adjusted rate is determined by subtracting fees collected prior to the effective date of the new rate and assessments collected under Section 31(d) during all of fiscal year 2012 from $1,321,000,000, which is the amount to be collected for fiscal year 2012. That difference is then divided by the revised estimate of the aggregate dollar volume of sales for the remainder of the fiscal year following the effective date of the new rate.

The Commission estimates that it will collect $597,429,581 in fees for the period prior to the effective date of the mid-year adjustment and $16,425 in assessments on round turn transactions in security futures products during all of fiscal year 2012. Using the methodology referenced in Part II above, the Commission estimates that the aggregate dollar volume of sales for the remainder of fiscal year 2012 following the effective date of the new rate will be $32,330,785,567,489. This amount reflects more recent information on the dollar amount of sales of securities than was available at the time of the setting of the initial fee rate for fiscal year 2012, and indicates a significant reduction in sales. Based on these estimates, and employing the mid-year adjustment mechanism established by statute, the uniform adjusted rate must be adjusted to $22.40 per million of the aggregate dollar amount of sales of securities.[12] The aggregate dollar amount of sales of securities subject to Section 31 fees is illustrated in Appendix A.

IV. Effective Date of the Uniform Adjusted Rate

Section 31(j)(4)(B) of the Exchange Act provides that a mid-year adjustment shall take effect on April 1 of the fiscal year in which such rate applies. Therefore, the exchanges and the national securities association that are subject to Section 31 fees must pay fees under Sections 31(b) and (c) at the uniform adjusted rate of $22.40 per million for sales of securities transacted on April 1, 2012, and thereafter until the annual adjustment for fiscal 2013 is effective.

V. Conclusion

Accordingly, pursuant to Section 31 of the Exchange Act,[13]

It is hereby ordered that each of the fee rates under Sections 31(b) and (c) of the Exchange Act shall be $22.40 per $1,000,000 of the aggregate dollar amount of sales of securities subject to these sections effective April 1, 2012.

By the Commission.

Elizabeth M. Murphy,

Secretary.

Appendix A

A. Baseline Estimate of the Aggregate Dollar Amount of Sales

First, calculate the average daily dollar amount of sales (ADS) for each month in the sample (January 2002–January 2012). The data obtained from the exchanges and FINRA are presented in Table A. The monthly aggregate dollar amount of sales from all exchanges and FINRA is contained in column C.

Next, calculate the change in the natural logarithm of ADS from month-to-month. The average monthly change in the logarithm of ADS over the entire sample is 0.007 and the standard deviation 0.126. Assume the monthly percentage change in ADS follows a random walk. The expected monthly percentage growth rate of ADS is 1.5 percent.

to the Commission by Congress for such fiscal year.'').

[5] *Id.*

[6] Order Making Fiscal Year 2012 Annual Adjustments to Transaction Fee Rates, Rel. No. 34–66202 (January 20, 2012).

[7] The amount $71,646,369,036,088 is the baseline estimate of the aggregate dollar amount of sales for fiscal year 2012 calculated by the Commission in its Order Making Fiscal Year 2012 Annual Adjustments to Transaction Fee Rates, Rel. No. 34–66202 (January 20, 2012).

[8] The Financial Industry Regulatory Authority, Inc. (''FINRA'') and each exchange is required to file a monthly report on Form R31 containing dollar volume data on sales of securities subject to Section 31. The report is due on the 10th business day following the month for which the exchange or association provides dollar volume data.

[9] Although Section 31(j)(2) indicates that the Commission should determine the actual aggregate dollar volume of sales for fiscal 2012 ''based on the actual aggregate dollar volume of sales during the first 5 months of such fiscal year,'' data are only available for the first four months of the fiscal year as of the date the Commission is required to issue this order, *i.e.,* March 1, 2012. Dollar volume data on sales of securities subject to Section 31 for February 2012 will not be available from the exchanges and FINRA for several weeks.

[10] *See* Appendix A.

[11] 15 U.S.C. 78ee(j)(2). The term ''fees collected'' is not defined in Section 31. Because national securities exchanges and national securities associations are not required to pay the first installment of Section 31 fees for fiscal 2012 until March 15, the Commission will not ''collect'' any fees in the first five months of fiscal 2012. *See* 15 U.S.C. 78ee(e). However, the Commission believes that, for purposes of calculating the mid-year adjustment, Congress, by stating in Section 31(j)(2) that the ''uniform adjusted rate * * * is reasonably likely to produce aggregate fee collections under Section 31 * * * that are equal to [$1,321,000,000],'' intended the Commission to include the fees that the Commission will collect based on transactions in the six months before the effective date of the mid-year adjustment.

[12] The calculation is as follows: ($1,321,000,000 − $597,429,581 − $16,425)/$32,330,785,567,489 = 0.0000223797. Round this result to the seventh decimal point, yielding a rate of $22.40 per million.

[13] 15 U.S.C. 78ee.

Now, use the expected monthly percentage growth rate to forecast total dollar volume. For example, one can use the ADS for January 2012 ($236,326,110,324) to forecast ADS for February 2012 ($239,879,615,120 = $236,326,110,324 × 1.015).[14] Multiply by the number of trading days in February 2012 (20) to obtain a forecast of the total dollar volume for the month ($4,797,592,302,406). Repeat the method to generate forecasts for subsequent months.

The forecasts for total dollar volume are in column G of Table A. The following is a more formal (mathematical) description of the procedure:

1. Divide each month's total dollar volume (column C) by the number of trading days in that month (column B) to obtain the average daily dollar volume (ADS, column D).

2. For each month t, calculate the change in ADS from the previous month as $\Delta_t = \log(ADS_t/ADS_{t-1})$, where log (x) denotes the natural logarithm of x.

3. Calculate the mean and standard deviation of the series $\{\Delta_1, \Delta_2, * * *, \Delta_{120}\}$. These are given by $\mu = 0.007$ and $\sigma = 0.126$, respectively.

[14] The value 1.015 has been rounded. All computations are done with the unrounded value.

4. Assume that the natural logarithm of ADS follows a random walk, so that Δ_s and Δ_t are statistically independent for any two months s and t.

5. Under the assumption that Δ_t is normally distributed, the expected value of ADS_t/ADS_{t-1} is given by $\exp(\mu + \sigma^2/2)$, or on average $ADS_t = 1.015 \times ADS_{t-1}$.

6. For February 2012, this gives a forecast ADS of 1.015 × $236,326,110,324 = $239,879,615,120. Multiply this figure by the 20 trading days in February 2012 to obtain a total dollar volume forecast of $4,797,592,302,406.

7. For March 2012, multiply the February 2012 ADS forecast by 1.015 to obtain a forecast ADS of $243,486,551,999. Multiply this figure by the 22 trading days in March 2012 to obtain a total dollar volume forecast of $5,356,704,143,984.

8. Repeat this procedure for subsequent months.

B. Using the Forecasts From A To Calculate the New Fee Rate

1. Determine the aggregate dollar volume of sales between 10/1/11 and 2/20/12 to be $24,520,003,895,923. Multiply this amount by the fee rate of $19.20 per million dollars in sales during this period and get $470,784,075 in actual and projected fees collected during 10/1/11 and 2/20/12. Determine the projected aggregate dollar volume of sales between 2/21/12 and 3/31/12 to be $7,035,861,449,826. Multiply this amount by the fee rate of $18.00 per million dollars in sales during this period and get an estimate of $126,645,506 in projected fees collected during 2/21/12 and 3/31/12.

2. Estimate the amount of assessments on security futures products collected during 10/1/11 and 9/30/12 to be $16,425 by summing the amounts collected through January 2012 of $5,716 with projections of a 1.5% monthly increase in subsequent months.

3. Determine the projected aggregate dollar volume of sales between 4/1/12 and 9/30/12 to be $32,330,785,567,489.

4. The rate necessary to collect $1,321,000,000 in fee revenues is then calculated as: ($1,321,000,000 − $470,784,075 − $126,645,506 − $16,425) ÷ $32,330,785,567,489 = 0.0000223797.

5. Round the result to the seventh decimal point, yielding a rate of 0.0000224000 (or $22.40 per million).

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Table A. Estimation of baseline of the aggregate dollar amount of sales.
(Methodology developed in consultation with the Office of Management and Budget and the Congressional Budget Office.)

Fee rate calculation.

a. Baseline estimate of the aggregate dollar amount of sales, 10/1/11 to 2/20/12 ($Millions)	24,520,004
b. Baseline estimate of the aggregate dollar amount of sales, 2/21/12 to 3/31/12 ($Millions)	7,035,861
c. Baseline estimate of the aggregate dollar amount of sales, 4/1/12 to 9/30/12 ($Millions)	32,330,786
d. Estimated collections in assessments on security futures products in FY 2012 ($Millions)	0.016
e. Implied fee rate (($1,321,000,000 - 0.0000192*a - 0.0000180*b - d) /c)	$22.40

Data

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Month	# of Trading Days in Month	Aggregate Dollar Amount of Sales	Average Daily Dollar Amount of Sales (ADS)	Change in LN of ADS	Forecast ADS	Forecast Aggregate Dollar Amount of Sales
Jan-02	21	2,149,243,312,432	102,344,919,640	-		
Feb-02	19	1,928,830,595,585	101,517,399,768	-0.008		
Mar-02	20	2,002,216,374,514	100,110,818,726	-0.014		
Apr-02	22	2,062,101,866,506	93,731,903,023	-0.066		
May-02	22	1,985,859,756,557	90,266,352,571	-0.038		
Jun-02	20	1,882,185,380,609	94,109,269,030	0.042		
Jul-02	22	2,349,564,490,189	106,798,385,918	0.126		
Aug-02	22	1,793,429,904,079	81,519,541,095	-0.270		
Sep-02	20	1,518,944,367,204	75,947,218,360	-0.071		
Oct-02	23	2,127,874,947,972	92,516,302,086	0.197		
Nov-02	20	1,780,816,458,122	89,040,822,906	-0.038		
Dec-02	21	1,561,092,215,646	74,337,724,555	-0.180		
Jan-03	21	1,723,698,830,414	82,080,896,686	0.099		
Feb-03	19	1,411,722,405,357	74,301,179,229	-0.100		
Mar-03	21	1,699,581,267,718	80,932,441,320	0.085		
Apr-03	21	1,759,751,025,279	83,797,667,870	0.035		
May-03	21	1,871,390,985,678	89,113,856,461	0.062		
Jun-03	21	2,122,225,077,345	101,058,337,016	0.126		
Jul-03	22	2,100,812,973,956	95,491,498,816	-0.057		
Aug-03	21	1,766,527,686,224	84,120,366,011	-0.127		
Sep-03	21	2,063,584,421,939	98,265,924,854	0.155		
Oct-03	23	2,331,850,083,022	101,384,786,218	0.031		
Nov-03	19	1,903,726,129,859	100,196,112,098	-0.012		
Dec-03	22	2,066,530,151,383	93,933,188,699	-0.065		
Jan-04	20	2,390,942,905,678	119,547,145,284	0.241		
Feb-04	19	2,177,765,594,701	114,619,241,826	-0.042		
Mar-04	23	2,613,808,754,550	113,643,858,893	-0.009		
Apr-04	21	2,418,663,760,191	115,174,464,771	0.013		
May-04	20	2,259,243,404,459	112,962,170,223	-0.019		
Jun-04	21	2,112,826,072,876	100,610,765,375	-0.116		
Jul-04	21	2,209,808,376,565	105,228,970,313	0.045		
Aug-04	22	2,033,343,354,640	92,424,697,938	-0.130		
Sep-04	21	1,993,803,487,749	94,943,023,226	0.027		
Oct-04	21	2,414,599,088,108	114,980,908,958	0.191		
Nov-04	21	2,577,513,374,160	122,738,732,103	0.065		
Dec-04	22	2,673,532,981,863	121,524,226,448	-0.010		
Jan-05	20	2,581,847,200,448	129,092,360,022	0.060		
Feb-05	19	2,532,202,408,589	133,273,810,978	0.032		
Mar-05	22	3,030,474,897,226	137,748,858,965	0.033		
Apr-05	21	2,906,386,944,434	138,399,378,306	0.005		
May-05	21	2,697,414,503,460	128,448,309,689	-0.075		
Jun-05	22	2,825,962,273,624	128,452,830,619	0.000		
Jul-05	20	2,604,021,263,875	130,201,063,194	0.014		
Aug-05	23	2,846,115,585,965	123,744,155,912	-0.051		
Sep-05	21	3,009,640,645,370	143,316,221,208	0.147		
Oct-05	21	3,279,847,331,057	156,183,206,241	0.086		
Nov-05	21	3,163,453,821,548	150,640,658,169	-0.036		
Dec-05	21	3,090,212,715,561	147,152,986,455	-0.023		

Jan-06	20	3,573,372,724,766	178,668,636,238	0.194		
Feb-06	19	3,314,259,849,456	174,434,728,919	-0.024		
Mar-06	23	3,807,974,821,564	165,564,122,677	-0.052		
Apr-06	19	3,257,478,138,851	171,446,217,834	0.035		
May-06	22	4,206,447,844,451	191,202,174,748	0.109		
Jun-06	22	3,995,113,357,316	181,596,061,696	-0.052		
Jul-06	20	3,339,658,009,357	166,982,900,468	-0.084		
Aug-06	23	3,410,187,280,845	148,269,012,211	-0.119		
Sep-06	20	3,407,409,863,673	170,370,493,184	0.139		
Oct-06	22	3,980,070,216,912	180,912,282,587	0.060		
Nov-06	21	3,933,474,986,969	187,308,332,713	0.035		
Dec-06	20	3,715,146,848,695	185,757,342,435	-0.008		
Jan-07	20	4,263,986,570,973	213,199,328,549	0.138		
Feb-07	19	3,946,799,860,532	207,726,308,449	-0.026		
Mar-07	22	5,245,051,744,090	238,411,442,913	0.138		
Apr-07	20	4,274,665,072,437	213,733,253,622	-0.109		
May-07	22	5,172,568,357,522	235,116,743,524	0.095		
Jun-07	21	5,586,337,010,802	266,016,048,133	0.123		
Jul-07	21	5,938,330,480,139	282,777,641,911	0.061		
Aug-07	23	7,713,644,229,032	335,375,836,045	0.171		
Sep-07	19	4,805,676,596,099	252,930,347,163	-0.282		
Oct-07	23	6,499,651,716,225	282,593,552,879	0.111		
Nov-07	21	7,176,290,763,989	341,728,131,619	0.190		
Dec-07	20	5,512,903,594,564	275,645,179,728	-0.215		
Jan-08	21	7,997,242,071,529	380,821,051,025	0.323		
Feb-08	20	6,139,080,448,887	306,954,022,444	-0.216		
Mar-08	20	6,767,852,332,381	338,392,616,619	0.098		
Apr-08	22	6,150,017,772,735	279,546,262,397	-0.191		
May-08	21	6,080,169,766,807	289,531,893,657	0.035		
Jun-08	21	6,962,199,302,412	331,533,300,115	0.135		
Jul-08	22	8,104,256,787,805	368,375,308,537	0.105		
Aug-08	21	6,106,057,711,009	290,764,652,905	-0.237		
Sep-08	21	8,156,991,919,103	388,428,186,624	0.290		
Oct-08	23	8,644,538,213,244	375,849,487,532	-0.033		
Nov-08	19	5,727,998,341,833	301,473,596,939	-0.221		
Dec-08	22	5,176,041,317,640	235,274,605,347	-0.248		
Jan-09	20	4,670,249,433,806	233,512,471,690	-0.008		
Feb-09	19	4,771,470,184,048	251,130,009,687	0.073		
Mar-09	22	5,885,594,284,780	267,527,012,945	0.063		
Apr-09	21	5,123,665,205,517	243,984,057,406	-0.092		
May-09	20	5,086,717,129,965	254,335,856,498	0.042		
Jun-09	22	5,271,742,782,609	239,624,671,937	-0.060		
Jul-09	22	4,659,599,245,583	211,799,965,708	-0.123		
Aug-09	21	4,582,102,295,783	218,195,347,418	0.030		
Sep-09	21	4,929,155,364,888	234,721,684,042	0.073		
Oct-09	22	5,410,025,301,030	245,910,240,956	0.047		
Nov-09	20	4,770,928,103,032	238,546,405,152	-0.030		
Dec-09	22	4,688,555,303,171	213,116,150,144	-0.113		
Jan-10	19	4,661,793,708,648	245,357,563,613	0.141		
Feb-10	19	4,969,848,578,023	261,570,977,791	0.064		
Mar-10	23	5,563,529,823,621	241,892,601,027	-0.078		
Apr-10	21	5,546,445,874,917	264,116,470,234	0.088		
May-10	20	7,260,430,376,294	363,021,518,815	0.318		
Jun-10	22	6,124,776,349,285	278,398,924,967	-0.265		
Jul-10	21	5,058,242,097,334	240,868,671,302	-0.145		
Aug-10	22	4,765,828,263,463	216,628,557,430	-0.106		
Sep-10	21	4,640,722,344,586	220,986,778,314	0.020		
Oct-10	21	5,138,411,712,272	244,686,272,013	0.102		
Nov-10	21	5,279,700,881,901	251,414,327,710	0.027		
Dec-10	22	4,998,574,681,208	227,207,940,055	-0.101		
Jan-11	20	5,043,391,121,345	252,169,556,067	0.104		
Feb-11	19	5,114,631,590,581	269,191,136,346	0.065		
Mar-11	23	6,499,355,385,307	282,580,668,926	0.049		
Apr-11	20	4,975,954,868,765	248,797,743,438	-0.127		
May-11	21	5,717,905,621,053	272,281,220,050	0.090		
Jun-11	22	5,820,079,494,414	264,549,067,928	-0.029		
Jul-11	20	5,189,681,899,635	259,484,094,982	-0.019		
Aug-11	23	8,720,566,877,109	379,155,081,613	0.379		

Sep-11	21	6,343,578,147,811	302,075,149,896	-0.227		
Oct-11	21	6,163,272,963,688	293,489,188,747	-0.029		
Nov-11	21	5,493,906,473,584	261,614,593,980	-0.115		
Dec-11	21	5,017,867,255,600	238,946,059,790	-0.091		
Jan-12	20	4,726,522,206,487	236,326,110,324	-0.011		
Feb-12	20				239,879,615,120	4,797,592,302,406
Mar-12	22				243,486,551,999	5,356,704,143,984
Apr-12	20				247,147,724,390	4,942,954,487,796
May-12	22				250,863,947,801	5,519,006,851,628
Jun-12	21				254,636,050,005	5,347,357,050,113
Jul-12	21				258,464,871,221	5,427,762,295,633
Aug-12	23				262,351,264,299	6,034,079,078,884
Sep-12	19				266,296,094,918	5,059,625,803,434

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66506; File No. SR–CME–2012–01]

Self-Regulatory Organizations; Chicago Mercantile Exchange, Inc.; Order Approving Proposed Rule Change To Amend Rules Relating to Credit Default Swap Guaranty Fund

March 2, 2012

I. Introduction

On January 23, 2012, Chicago Mercantile Exchange Inc. (''CME'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–CME–2012–01 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on February 1, 2012.[3] The Commission received no comment letters regarding the proposal. For the reasons discussed below, the Commission is granting approval of the proposed rule change.

II. Description

The rule change would replace CME's ''aggregate performance bond requirement'' standard, which determines how CME calculates each CDS Clearing Member's allocation to the CDS Guaranty Fund, with a new standard that CME believes better allocates tail risk. Currently CME rules provide that each CDS Clearing Member's allocation to the CDS Guaranty Fund will be the greater of (i) $50,000,000 and (ii) its proportionate share of the 90-day trailing average of its aggregate performance bond requirements and average gross notional open interest outstanding at the Clearing House. The proposal would change the CDS Guaranty Fund so that the allocation will be made on the basis of each CDS Clearing Member's potential residual loss (''PRL''). PRL is a stress test of the tail risk CDS Clearing Member portfolios bring to the market. CME is also proposing to make conforming changes to its CDS Manual of Operations.

III. Discussion

Section 19(b)(2)(B) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[4] In particular, Section 17A(b)(3)(F)[5] of the Act requires, among other things, that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.

The proposed rule change would allow CME to change the method used for calculating individual CDS Clearing Member contributions to the CDS Guaranty Fund and is designed to more accurately align the allocation of its CDS Guaranty Fund requirement to CDS Clearing Members based on the risk presented by each such member. Thus, the proposed rule change to change CME's CDS Guaranty Fund allocation is consistent with the requirement in Section 17A(b)(3)(F) that CME safeguard the securities and funds which are in the custody or control of CME or for which it is responsible.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act and the rules and regulations thereunder.

It Is Therefore Ordered, pursuant to Section 19(b)(2)[6] of the Act, that the proposed rule change (File No. SR–CME–2012–01) be, and hereby is, approved.[7]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–5513 Filed 3–6–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66497; File No. SR–Phlx–2012–23]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Proposed Rule Change To Amend Registration and Qualification Requirements

March 1, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1], and Rule 19b–4[2] thereunder, notice is hereby given that on February 16, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–66250 (January 26, 2012), 77 FR 5070 (February 1, 2012). In its filing with the Commission, CME included statements concerning the purpose of and basis for the proposed rule change. The text of these statements is incorporated into the discussion of the proposed rule change in Section II below.

[4] 15 U.S.C. 78s(b)(2)(B).

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 15 U.S.C. 78s(b)(2).

[7] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete Rule 604 as well as amend and adopt several new rules governing the registration and qualification of members and persons associated with [3] member organizations, as described below. The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to strengthen the Exchange's current registration provisions in a number of ways. In 2010,[4] in connection with the Exchange's proposal to launch the Exchange's equity trading platform for NMS Stocks, NASDAQ OMX PSX (''PSX''),[5] the Exchange amended Rule 604 to adopt paragraph (h) to govern the registration of representatives and Supplementary Material .04 to Rule 604 regarding the specific category of such registration. In addition, with respect to principal registration, the Exchange adopted paragraph (g), Principal Registration, and Supplementary Material .01–.03 governing the specific categories of principal registration, to require that every member organization covered by those rules have at least two registered principals as well as a Financial/Operations Principal. The Exchange also adopted paragraph (i) to establish which persons are exempt from registration. These provisions became applicable only to PSX users pursuant to paragraph (f). In that filing, the Exchange stated:

''The Exchange intends to separately revise its registration and qualification rules related to activity other than business conducted on PSX, including its options business. The Exchange understands that other self-regulatory organizations are expected to adopt a framework that requires more fulsome registration and qualification requirements clearly spelled out in rules. The Exchange supports the Commission's commitment to ensure that such rules are adopted by all self-regulatory organizations on a consistent basis.''

Accordingly, the Exchange is now proposing to extend the principal and representative registration requirements of Rule 604(g) and (h) to all members, member organizations and associated persons by adopting Rules 611–616 to replace Rule 604. As a result of the new registration requirements, additional persons will become subject to the Exchange's continuing education requirement in Rule 640.

Background and Current Requirements

Currently, Rules 604(a)–(e) apply to all member organizations and generally require the Series 7 examination for Registered Representatives,[6] off-floor traders [7] and persons compensated directly or indirectly for the solicitation or handling of business in securities who are not otherwise required to register with the Exchange by Rule 604(a).[8] Furthermore, Rule 604(f) provides that members and persons associated with member organizations that are registered with the Exchange for the purpose of trading NMS Stocks [9] through the facilities of the Exchange, which is the PSX platform, are subject to the provisions of Rule 604(g) and (h) governing principal and representative registration, respectively. Thus, these provisions currently cover members that trade on PSX, and are substantially similar to the rules of The NASDAQ Stock Market LLC (''NASDAQ''), Financial Industry Regulatory Authority (''FINRA'') and NASDAQ OMX BX, Inc. (''BX'') requiring PSX users to register and qualify representatives and principals with the Exchange in accordance with such rules.

Proposal

The Exchange is proposing to extend the current principal requirement beyond PSX users to include all member organizations, including those who trade options. This more extensive principal requirement will be embodied in new Rules 611 and 612, which are substantially similar to current Rule 604(g) and Supplementary Material .01–.03.

In connection with strengthening its registration rules, the Exchange is proposing to reorganize and renumber its registration rules to better align with those of NASDAQ and FINRA, albeit within its own rule numbering structure. The following summarizes the new rule numbering structure:

Current phlx rule #	Topic	New phlx rule #	NASDAQ
604(g)	Principal Registration	611	1021
604.01–.03	Categories of Principal Registration	612	1022
604(h)	Representative Registration	613	1031
604.04	Categories of Representative Registration	613	1032
604(i)	Persons Exempt from Registration	614	1060
604(j)	Waiver	615	1070(d)
None	Electronic Filing	616	1140

[3] The term ''associated person'' or ''person associated with'' a member organization means any partner, officer, director, or branch manager of an Exchange member organization or applicant (or person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with such member organization or applicant, or any employee of such member or applicant, except that any person associated with a member organization or applicant whose functions are solely clerical or ministerial shall not be included in the meaning of such term for purposes of the Exchange Rules. *See* Rule 1(b).

[4] *See* Securities Exchange Act Release No. 62776 (August 26, 2010), 75 FR 53727 (September 1, 2010) (SR–Phlx–2010–91).

[5] *See* Securities Exchange Act Release No. 62877 (September 9, 2010), 75 FR 56633 (September 16, 2010) (SR–Phlx–2010–79).

[6] *See* Rule 604(a).

[7] *See* Rule 604(e).

[8] *See* Rule 604(d).

[9] *See* Rule 1(t).

Representative Registration

Rule 604(h) currently governs the registration of representatives [10] with the Exchange; specifically, Rule 604(h)(1) requires that all persons engaged or to be engaged in the investment banking or securities business [11] of a member organization who are to function as representatives shall be registered as such with the Exchange through WebCRD [12] in the category of registration appropriate to the function to be performed as specified in Supplementary Material .04 of Rule 604. Before their registration can become effective, they shall pass the Series 7 examination. Rule 604(h) is applicable today only to PSX users pursuant to Rule 604(f).

The provisions currently contained in Rule 604(h) are proposed to be moved to new Rule 613, Representative Registration, in substantially the same form, except with respect to trading floor personnel subject to Rule 620. Specifically, new Rule 613(a) will expressly state that, except members whose activities are limited to the Exchange's options trading floor and who are registered pursuant to Rule 620(a) as well as associated persons whose activities are limited to the Exchange's options trading floor and are registered pursuant to Rule 620(b), all persons engaged or to be engaged in the investment banking or securities business of a member organization who are to function as representatives shall be registered as such with the Exchange through WebCRD in the category of registration appropriate to the function to be performed as specified in Rule 613(e). This is the only change to the language currently in Rule 604(h) that is being moved to new Rule 613.

Accordingly, trading floor personnel will continue to be required to register pursuant to Rule 620, in lieu of new Rule 613,[13] such that trading floor personnel will not be required to successfully complete the Series 7 examination, as long as their activities are limited to the trading floor. The Exchange believes that it is appropriate to permit trading floor members and associated persons to operate pursuant to a registration and qualification framework tailored to their specific functions. These functions include handling and executing electronic and phoned-in orders on the trading floor, as well as providing markets, both verbally and electronically. Members on the trading floor will continue to be subject to the Exchange's Trading Floor Qualification Examination in lieu of the Series 7, which the Exchange believes is appropriate because the examination focuses on the rules and procedures most applicable to floor members.[14] For example, there are questions regarding the quoting obligations of Rule 1014(b), crossing orders pursuant to Rule 1064, and Floor Broker obligations in Rule 1063.

Respecting trading floor members, Rule 620 requires registration on Form U4 through WebCRD. Rule 620 will now require all trading floor personnel, including clerks, interns and any other associated persons, of a member organization not required to register pursuant to Rule 620(a) to register on Form U4 through WebCRD. Accordingly, the same registration information will be available electronically within WebCRD for trading floor members and associated persons as is available for persons registered as General Securities Representatives.

In terms of the actual category of registration that applies, currently, Supplementary Material .04 to Rule 604, titled Categories of Representative Registration—General Securities Representative, contains the basic requirement [15] that each member and each person associated with a member organization who is included within the definition of a representative in Rule 1(cc) is required to register with the Exchange as a General Securities Representative and shall pass the Series 7 examination before such registration may become effective. The appropriate registration category on WebCRD is ''GS.'' This provision is not changing, and was intended to capture traditional securities personnel in a rule similar to that of several other SROs.[16] The Exchange continues to believe that this provision is broad and should not generate gaps that permit a member organization to operate differently than under the registration rules of BX, NASDAQ or FINRA. The Exchange proposes to move the provisions of Rule 604(h) into Rule 613 and Supplementary Material .04 of Rule 604 into Rule 613(e). The Exchange believes that it is clearer to place the ''registered representative'' requirement and category of registration all in one rule, even though that differs from the FINRA and NASDAQ rules slightly.

The Exchange also proposes to adopt a new limited category of representative registration as Rule 613(f). The Exchange has been working with other exchanges and FINRA to develop a registration category and qualification examination for proprietary traders in lieu of the Series 7, which is now available through WebCRD. Accordingly, the Exchange proposes to recognize the new registration category, Proprietary Trader, and related examination, the Series 56,[17] and to incorporate it into Rule 613(f), subject to filing the Series 56 content outline with the Commission.[18] The Exchange intends to file the Series 56 content outline with the Commission shortly.[19] Proposed Rule 613(f) would provide that members and associated persons engaged solely in proprietary trading, market making or effecting transactions on behalf of a broker-dealer account may register instead as a Proprietary Trader and pass the Series 56 examination.[20] The term ''persons engaged in effecting transactions on behalf of a broker-dealer account'' is equivalent to persons engaged in proprietary trading or market making, because it covers persons who do not deal with the public. For example, this would include both Floor Brokers on the Exchange's trading floor as well as persons performing brokerage functions

[10] The term ''representative'' is defined in Rule 1 as a member or an associated person of a registered broker or dealer, including assistant officers other than principals, who is engaged in the investment banking or securities business for the member organization including the functions of supervision, solicitation or conduct of business in securities or who is engaged in the training of persons associated with a broker or dealer for any of these functions. To the extent provided in Rule 604, all representatives are required to be registered with the Exchange, and representatives that are so registered are referred to herein as ''Registered Representatives.'' *See* Rule 1(cc).

[11] The term ''investment banking or securities business'' means the business, carried on by a broker or dealer, of underwriting or distributing issues of securities, or of purchasing securities and offering the same for sale as a dealer, or of purchasing and selling securities upon the order and for the account of others. *See* Rule 1(m). Of course, the federal securities laws may require broker-dealers to become members of the FINRA in order to perform some of these functions. *See e.g.,* 15 U.S.C. 78o(b)(8).

[12] WebCRD is FINRA's automated Central Registration Depository.

[13] However, trading floor personnel and members on the trading floor will be subject to new principal registration requirements, as described below.

[14] The Exchange recently revised this examination. *See* Securities Exchange Act Release No. 63603 (December 22, 2010), 75 FR 82419 (December 30, 2010) (SR–Phlx–2010–180).

[15] This provision is the same as BX Rule 1032.

[16] *See e.g.,* BX Rules 1031 and 1032, NASDAQ rules 1031 and 1032, and NASD Rules 1031 AND 1031.

[17] This new examination, the Series 56, would also serve as a prerequisite for a new principal registration category, which the Exchange would recognize; the Series 24 would be the appropriate examination for the new principal registration category, as described below.

[18] *See e.g.,* Securities Exchange Act Release No. 64699 (June 17, 2011) (SR–CBOE–2011–056).

[19] The Exchange is also proposing that the Series 56 serve as a prerequisite to the Series 24, as described further below.

[20] *See supra* note 17.

off the trading floor (''upstairs'').[21] The Exchange believes that the Series 56 helps ensure that such persons are qualified, because it addresses industry topics that establish the foundation for the regulatory and procedural knowledge necessary for individuals required to register as a Proprietary Trader.

The Exchange is proposing to delete Rule 604 in its entirety.[22] With respect to paragraphs (a), (d) and (e), the Exchange believes that the requirements of new Rule 613 cover every person subject to registration as a representative and the Series 7 examination. The Exchange believes that Rule 613 is broader, because it is not limited to member organizations for which the Exchange is the designated examining authority (''DEA'') nor is it limited to specific categories of persons, such as Rule 604(e). In addition, the language of Rule 613 more closely aligns with the rules of FINRA and NASDAQ, which should facilitate compliance by broker-dealers. Thus, although Rule 604 is being deleted, the same persons will continue to be required to successfully complete the Series 7 examination and be registered as a ''Registered Representative'' on Form U4 through WebCRD. This proposal will extend the requirements of Rule 604(h) to all member organizations, whereas today Rule 604(h) only applies to member organizations registered to use PSX.[23]

Principal Registration

With respect to principal registration on the Exchange, Rule 604(g)[24] currently provides that certain member organizations must register at least two principals with the Exchange,[25] unless an exception applies. The Exchange is proposing to adopt new Rule 611, Principal Registration, and to move the provisions of existing Rule 604(g) over into this new rule. Accordingly, the principal registration rules will now apply beyond PSX users to all Phlx member organizations, with the addition of two new registration categories to satisfy the principal requirement: Registered Options Principal and Proprietary Trader Principal.

Phlx rules will require that each principal must successfully complete the General Securities Principal Examination (''Series 24'') and submit a Form U4 via WebCRD reflecting registration as such, using the category ''GP,'' unless a different category of principal registration applies to such person. Specifically, new Rule 611 will provide that all persons engaged or to be engaged in the investment banking or securities business of a member organization who are to function as principals shall be registered as such with the Exchange through WebCRD in the category of registration appropriate to the function to be performed as specified in Rule 612, Categories of Principal Registration, which replaces existing Supplementary Material .01–.03 of Rule 604. Before their registration can become effective, they shall pass a qualification examination for principals appropriate to the category of registration. Persons associated with a member organization who are actively engaged in the management of the member organization's investment banking or securities business, including supervision, solicitation, conduct of business or the training of persons associated with a member organization for any of these functions are principals. Such persons shall include: sole proprietors, officers, partners, managers of offices of supervisory jurisdiction,[26] and directors of corporations. This requirement will now appear in Rule 611(b) and apply to all member organizations.

Rule 604(g)(5) currently requires at least two registered principals, which will now be contained in new Rule 611(e).[27] Specifically, an Exchange member organization, except a sole proprietorship, shall have at least two officers or partners who are registered as principals with respect to each aspect of the member organization's investment banking and securities business pursuant to the applicable provisions of Rule 611; provided, however, that a proprietary trading firm[28] with 25 or fewer registered representatives shall only be required to have one officer or partner who is registered as a principal. This exception to the two principal requirement is similar to that of several other exchanges and reflects that such firms do not necessitate the same level of supervisory structure as firms who have customers or larger firms. This exception is not changing and will now be in Rule 611(e)(i), applicable to all member organizations.[29]

Rule 611(e)(ii) will provide, like Rule 604(g) currently does, that the Exchange may waive the two principal requirement in situations that indicate conclusively that only one person should be required to register as a principal. This provision is identical to that of several other exchanges, and the Exchange believes that such waiver is appropriate in certain situations, but should be carefully applied; for example, the Exchange may determine to apply this provision to a very small firm, with only a few employees in one location.

To help determine how a person should register as a principal, Supplementary Material .01–.03 to Rule 604 currently enumerates the three categories of principal registration. These categories will now be in new Rule 612. First, Rule 604.01, titled General Securities Principal, provides that each member or person associated with a member organization who is included within the definition of

[21] This provision is the same as the provision in Chicago Board Options Exchange Incorporated (''CBOE'') rules which requires that an individual Permit Holder or associated person who effects transactions on behalf of a broker-dealer account register and pass the Series 56 examination. *See* CBOE Rule 3.6A, Interpretation and Policy .06.

[22] The Exchange proposes to amend the following additional rules to replace references to Rule 604 with the new applicable rule number: Rule 1(cc), Rule 1090, Rule 3202, Equity Floor Procedure Advice (''EFPA'') A–7 and Options Floor Procedure Advice (''OFPA'') F–34. Rule 3202 will now refer to the applicability of Rules 611–616 to PSX users.

[23] *See* Rule 604(f).

[24] This rule is similar to NASDAQ Rule 1021, BX Rule 1021 and NASD Rule 1021.

[25] All persons who engage in specified supervisory functions will be registered as principals. All principals are first required to register as and qualify as Representatives.

[26] The Exchange defined the term ''office of supervisory jurisdiction'' to mean any office of a member organization at which any one or more of the following functions take place: order execution and/or market making; structuring of public offerings or private placements; maintaining custody of customers' funds and/or securities; final acceptance (approval) of new accounts on behalf of the member organization; review and endorsement of customer orders; final approval of advertising or sales literature for use by persons associated with the member organization, pursuant to Rule 605, except for an office that solely conducts final approval of research reports; or responsibility for supervising the activities of persons associated with the member organization at one or more other branch offices of the member organization. This definition is drawn from NASD Rule 3010. The Exchange is adopting the reference to this term in order to cover these managers in the new principal registration requirement. The Exchange is not, at this time, adopting a comprehensive program with regard to such offices, such as that found in NASD Rule 3010. *See* proposed Rule 611(b).

[27] All persons who engage in specified supervisory functions must be registered as Principals.

[28] The term ''proprietary trading firm'' means a member organization or applicant with the following characteristics: (A) The applicant is not required by Section 15(b)(8) of the Act to become a FINRA member but is a member of another registered securities exchange not registered solely under Section 6(g) of the Act; (B) all funds used or proposed to be used by the applicant for trading are the applicant's own capital, traded through the applicant's own accounts; (C) the applicant does not, and will not have customers; and (D) all Principals and Representatives of the applicant acting or to be acting in the capacity of a trader must be owners of, employees of, or contractors to the applicant. *See* proposed Rule 611(e)(i).

[29] Member organizations operating on the trading floor will be subject to the minimum ''two principal'' requirement, except to the extent that the ''proprietary trading firm'' exception permits certain firms to have one principal.

principal, and each person designated as a Chief Compliance Officer on Schedule A of Form BD shall be required to register with the Exchange as a General Securities Principal and shall pass the Series 24 examination before such registration may become effective, unless such person's activities are so limited as to qualify such person for one or more of the limited categories of principal registration specified in Rule 612.[30] The Exchange proposes to move these provisions of Rule 604.01 to new Rule 612(a), also titled General Securities Principal.

The Exchange also proposes to recognize two new principal registration categories. First, the Exchange proposes to adopt Rule 612(d) in order to permit Registered Options Principals to satisfy the principal registration requirements of Rule 611. Specifically, each member or person associated with a member organization who is included within the definition of principal, and each person designated as a Chief Compliance Officer on Schedule A of Form BD of a member organization may register as a Registered Options Principal and successfully complete the Series 4 examination, instead of registering as a General Securities Principal and successfully completing the Series 24 examination, if such person's activities are limited solely to options. Specifically, Rule 612(d) will provide that such person's supervisory responsibilities in the investment banking and securities business must be limited to the options activities of a member organization, that he or she must be registered pursuant to Exchange Rules as a General Securities Representative, that he or she is qualified to be so registered by passing the Series 4 examination, and that he or she shall not be qualified to function in a principal capacity with responsibility over any area of business activity other than the supervision of persons involved exclusively in options activity. The Exchange believes that the Registered Options Principal category is appropriate for a principal whose activities are limited solely to options.[31] The Series 4 examination covers options-related topics, which should help ensure that principals whose activities are limited to options are properly qualified. Furthermore, Rule 1024 currently requires persons who supervise options sales practice activities to register as a Registered Options Principal; thus, the Exchange believes that some member organizations have already registered certain associated persons in this category, such that these persons could satisfy the new principal registration requirement for applicable firms.

Second, the Exchange proposes to recognize the new Proprietary Trader Principal category as a limited principal category in Rule 612(e). It would apply to persons whose supervisory responsibilities in the investment banking and securities business are limited to the activities of a member organization that involve proprietary trading, market making and effecting transactions on behalf of broker-dealers. It would require that he or she be registered pursuant to Exchange Rules as a Proprietary Trader, be qualified to be so registered by passing the Series 24 examination, and not function in a principal capacity with responsibility over any area of business activity other than proprietary trading, market making and effecting transactions on behalf of broker-dealer accounts.

The Exchange has been working with other exchanges and FINRA to develop this registration category, which is limited to persons who supervise persons engaged in proprietary trading, market making or effecting transactions on behalf of broker-dealer accounts.[32] This category is in lieu of registration as a General Securities Principal, for which the prerequisite qualification examination is the Series 7. The appropriate qualification examination for the proposed new registration category of Proprietary Trader Principal is the Series 24, which is the same qualification required for registration as a General Securities Principal; no new examination has been developed. However, the prerequisite examination for the new Proprietary Trader Principal category is the new Series 56, which is described above. Accordingly, a person who has passed the Series 56 can register as a Proprietary Trader Principal and take the Series 24 examination, under this proposal, but cannot register as a General Securities Principal without first qualifying as a General Securities Representative and passing the Series 7. Thus, although the Series 24 will now be the appropriate qualification examination for both categories (General Securities Principal and Proprietary Trader Principal), different prerequisites apply and different registration categories result.

The new Proprietary Trader Principal category is expected to become available to Phlx member organizations in WebCRD soon and the Exchange will communicate the implementation date to the membership. The Exchange believes that the new principal registration category is an appropriate corollary to the new representative registration category discussed above and reflects a substantial joint-exchange effort to develop a registration framework specific to principals supervising persons engaged in proprietary trading, market making and effecting transactions on behalf of broker-dealer accounts. Furthermore, the Exchange believes that the Series 24 is the appropriate examination for Proprietary Trader Principals, because it tests knowledge and understanding of supervision-related rules.

Both the Registered Options Principal and the Proprietary Trader Principal registrations count towards the minimum two principal requirement in Rule 611. The Exchange believes that this is appropriate because both of these principals are subject to a comprehensive qualification examination that covers their area of supervision. Of course, if the member organization is involved in activity other than what a Proprietary Trader Principal and a Registered Options Principal are permitted under these rules to supervise, an additional principal would be required.

Two other provisions of the current principal registration framework are also becoming applicable to all member organizations, in addition to the basic principal requirement. Rule 604.02, titled Limited Principal—Financial and Operations, currently requires that each member organization of the Exchange that is subject to Rule 604(g) and that is operating pursuant to the provisions of SEC Rule 15c3–1(a)(1)(ii), (a)(2)(i) or (a)(8), designate as Limited Principal—Financial and Operations (''FINOP'') those persons associated with it, at least one of whom shall be its chief financial officer, who perform the following duties: final approval and responsibility for the accuracy of financial reports submitted to any duly established securities industry regulatory body; final preparation of such reports; supervision of individuals who assist in the preparation of such reports; supervision of and responsibility for individuals who are involved in the actual maintenance of the member organization's books and records from which such reports are derived; supervision and/or performance of the

[30] However, pursuant to Rule 604.01(c), a person registered solely as a General Securities Principal shall not be qualified to function as a FINOP or a Limited Principal—General Securities Sales Supervisor unless that person is also qualified and registered as such.

[31] This is similar to BATS Exchange, Inc. (''BATS'') Rule 17.1(g).

[32] In effect, supervisors who supervise persons engaged only in activities covered by the proposed new Proprietary Trader registration category can meet the principal registration requirement by registering as a Proprietary Trader Principal.

member organization's responsibilities under all financial responsibility rules promulgated pursuant to the provisions of the Act; overall supervision of and responsibility for the individuals who are involved in the administration and maintenance of the member organization's back office operations; or any other matter involving the financial and operational management of the member organization. Each FINOP must register with the Exchange and pass the Series 27 examination. The Exchange proposes to move this provision to Rule 612(b) and extend it beyond PSX users, including trading floor members. This provision is intended to ensure that persons handling the financial affairs of a firm are properly registered and qualified. This requirement also harmonizes the Exchange's rules with those of other exchanges [33] and recognizes the importance and complexity of the rules governing financial responsibility for broker-dealers.[34] Although the FINOP is a type of principal registration, because its scope is limited to financial matters, the FINOP does not count toward the two principal requirement of Rule 611.

Rule 604.03, Limited Principal—General Securities Sales Supervisor, is also being extended to all member organizations as new Rule 612(c). It currently provides that each person associated with a member organization who is included in the definition of principal in Rule 604(g) (changing to Rule 611) may register with the Exchange as a Limited Principal—General Securities Sales Supervisor, or ''SU,'' if applicable. This provision is being moved, unchanged, in its entirety to new Rule 612(c). Like the FINOP, the General Securities Sales Supervisor does not count toward satisfying the two principal requirement of Rule 611.

In total, although various other supervisory rules currently operate, such as Phlx Rule 748,[35] extending these principal registration requirements beyond Exchange member organizations doing business on PSX should strengthen the framework of supervisory rules. The Exchange believes that the broader application of the principal registration requirement is an important change. The Exchange also believes that offering categories of limited principal registration should help ensure that principals are properly qualified for their specific functions, such as supervising persons involved in options and proprietary trading.

Other Rules

The Exchange proposes to renumber Rule 604(i), Persons Exempt from Registration, as new Rule 614. No changes are proposed thereto. These registration exemptions will now apply to all member organizations and are intended to make clear that registration of certain, specific persons is not necessary, because of their functions. This provision is based on exemptions contained in, for example, NASDAQ Rule 1060 and BX Rule 1060.

Rule 604(i)(2) provides that member organizations, and persons associated with a member organization, may pay nonregistered foreign persons transaction-related compensation based upon the business of customers they direct to member organizations under certain conditions detailed in the rule. This provision is intended to cover the payment of fees to finders,[36] and is being moved to Rule 614(b), without change.

The Exchange proposes to renumber Rule 604(j) as Rule 615, Waiver of Requirements. Currently, Rule 604(j) provides that the Exchange may, in exceptional cases and where good cause is shown, waive the applicable Qualification Examination and accept other standards as evidence of an applicant's qualifications for registration. Advanced age or physical infirmity will not individually of themselves constitute sufficient grounds to waive a Qualification Examination. Experience in fields ancillary to the investment banking or securities business may constitute sufficient grounds to waive a Qualification Examination. The rule is not changing and is based on corresponding rules of FINRA, NASDAQ and BX.

The Exchange proposes to adopt Rule 616, Electronic Filing Requirements for Uniform Forms. Rule 616(a), WebCRD Filing, will provide that forms required to be filed under the Rule 600 Series shall be filed electronically through WebCRD.[37] Currently, some of the rules in the 600 series state this and others do not, such that adopting a separate, new rule should be clearer. Similarly, new Rule 616(b), Form U4 and U5 Filing Requirements, will require that initial filings and amendments of Forms U4 and U5 be submitted electronically. Furthermore, as part of the member organization's recordkeeping requirements, it shall retain such records for a period of not less than three years, the first two years in an easily accessible place, in accordance with Exchange Act Rule 17a–4, and make such records available promptly upon regulatory request. In addition, every application for registration filed with the Exchange shall be kept current at all times by supplementary amendments via electronic filing or such other process as the Exchange may prescribe. Such amendments shall be filed not later than 30 days after the applicant learns of the facts or circumstances giving rise to the need for the amendment. These requirements also currently may appear in various rules but not each applicable rule, such that adopting a separate, new rule should be clearer.[38]

The Exchange also proposes to amend OFPA F–34 and EFPA A–7, both titled Failure to Timely Submit Amendments to Form U4, Form U5 and Form BD; these are the corollary minor rule plan provisions for Rule 623, which are being amended only to add new rule numbers 611–613 and 616 and to delete reference to Rule 604.

The Exchange proposes to amend Rule 620, Trading Floor Registration, to specifically state the registration categories governed by the rule, to require all trading floor associated persons of member organizations to register via Form U4, to delete unnecessary language and to strengthen a time requirement. Specifically, the Exchange proposes to add to Rule 620(a), which requires the registration of Floor Brokers, Specialists and Registered Options Traders on an Exchange trading floor via Form U4, that the appropriate registration category on such form is ''Member Exchange (''ME'')'' under ''PHLX.'' This is intended to specify registration categories in the Exchange's rules whenever possible, for clarity. The Exchange notes that this provision covers members operating on the trading floor and that such members are required to successfully complete the Exchange's Trading Floor Qualification Examination. The Exchange also proposes to delete a reference in Rule 620(a) to updating Form U4 within a certain time period, because this requirement will now appear in new Rule 616, as explained above.

Currently, Rule 620(b) covers all trading floor personnel, such as clerks, interns, and other associated persons of member organizations, not required to register under Rule 620(a) and requires

[33] *See e.g.,* CBOE Rule 3.6A(b).

[34] *See e.g.,* Phlx Rule 703.

[35] Currently, Rule 748, Supervision, establishes the supervisory requirement for member organizations, including that all locations and activities of a member organization be supervised by a qualified supervisor.

[36] This provision is identical to NASDAQ Rule 1060(b) and BX Rule 1060(b).

[37] This is similar to International Securities Exchange, LLC (''ISE'') Rules 313.01 and .02.

[38] This rule is similar to NASDAQ Rule 1031(d)(3).

them to register with the Exchange on a form supplied by the Exchange. The Exchange proposes to significantly strengthen this requirement by requiring these individuals to be registered on Form U4 on WebCRD, not just with the Exchange. Accordingly, these associated persons will be subject to the comprehensive disclosure obligations of Form U4, which the Exchange believes is an important enhancement. For example, once a Form U4 submission is required, the background information of these individuals will be available electronically within WebCRD for access by the appropriate regulators. The specific registration category will be ''Floor Employee (''FE'')'' under ''PHLX,'' which will be stated expressly in the rule. The Exchange does not intend to require a qualification examination for non-member trading floor personnel at this time. The Exchange does not believe that the Series 7, Series 56 or the Exchange's own Trading Floor Qualification Examination are appropriate for the limited functions of a trading floor clerk, because these persons are not members trading on the floor and they are supervised by members. These persons do not execute transactions on the Exchange, but rather enter orders and report trades, for example, and related clerical functions.[39] Specifically, the types of questions covered by the Exchange's Trading Floor Qualification Examination include announcing trades, trade allocation and floor broker responsibilities, all of which are rules that apply to trading floor members, but not clerks or off-floor persons.

The Exchange also proposes to amend Rule 620(b) to provide that following the termination of, or the initiation of a change in the status of any such personnel of a member organization who has been issued an Exchange access card and a trading floor badge, the appropriate Exchange form must be completed, approved and dated by a member organization principal, officer, or member of the member organization with authority to do so, and submitted to the appropriate Exchange department no later than 9:30 a.m. the next business day by the member organization employer. The Exchange proposes to strengthen this requirement by adding that such submission should occur, rather than no later than 9:30 a.m. the next business day, as soon as possible but no later than 9:30 a.m. the next business day.

Lastly, the Exchange proposes to amend Rule 623, Fingerprinting, to adopt a new paragraph (b), which is similar to NASDAQ Rule 1140(d). Upon filing an electronic Form U4 pursuant to Rule 616 on behalf of a person applying for registration, a member shall promptly submit fingerprint information for that person. The Exchange may make a registration effective pending receipt of the fingerprint information. The fingerprinting requirement is not new, but rather is being codified into the appropriate rule.[40]

Conclusion

The Exchange believes that these proposed new rules should form a solid framework for the registration and qualification of all member organizations and their personnel. As a result of the new registration requirements, additional persons will become subject to the Exchange's continuing education requirement in Rule 640. The Exchange will announce to the membership when these new requirements will be implemented and available for member organizations to access.

The Exchange proposes to require that member organizations comply with the new registration and qualification requirements within 90 days of the Exchange's issuance of an alert to its membership, announcing Commission approval; respecting any registration category and related examination that has a prerequisite, the Exchange proposes to require its member organizations to comply therewith 90 days after successful completion of the prerequisite exam.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[41] in general, and furthers the objectives of: (1) Section 6(c)(3)(B) of the Act,[42] pursuant to which a national securities exchange prescribes standards of training, experience and competence for members and their associated persons; and (2) Section 6(b)(5) of the Act,[43] in that it is designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, by extending its registration and qualification requirements beyond PSX users. Overall, as discussed in more detail above, the Exchange believes that these new requirements bolster the integrity of the Exchange by helping to ensure that all associated persons engaged in a securities business are, and will continue to be, properly trained and qualified to perform their functions, will be supervised, and can be identified by regulators.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2012–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2012–23. This file number should be included on the

[39] *See* Rule 1090.

[40] OFPA F–25 and EFPA A–4 are the corollary minor rule plan provisions for Rule 623; these are not changing.

[41] 15 U.S.C. 78f(b).

[42] 15 U.S.C. 78(c)(3)(B).

[43] 15 U.S.C. 78f(b)(5).

subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2012–23 and should be submitted on or before March 28, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–5555 Filed 3–6–12; 8:45 am]

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[44] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66503; File No. SR–CHX–2012–02]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Order Approving a Proposed Rule Change To Add to and Amend Its Rules Regarding the Obligations of Institutional Brokers Registered With the Exchange

March 1, 2012.

I. Introduction

On January 6, 2012, the Chicago Stock Exchange, Inc. (''CHX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to permit broker-dealers registered as Institutional Brokers with CHX to operate a non-Institutional Broker unit within the same Participant Firm. The proposed rule change was published for comment in the **Federal Register** on January 24, 2012.[3] The Commission received no comment letters on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

Institutional Brokers are an elective sub-category of Exchange Participants who are subject to the obligations of Article 17 of the CHX rules. Registration as an Institutional Broker is limited to Participant Firms, and is not available to individual persons.[4] Under current CHX rules, each individual person authorized to enter bids and offers and execute transactions on behalf of an Institutional Broker is considered an Institutional Broker Representative (''IBR'') and must be registered with the Exchange as provided in Article 6.

Institutional Brokers are the successors to the floor brokers that operated within the Exchange's previous floor-based, auction trading model. The Exchange replaced its floor-based, auction trading model with its New Trading Model, which features an electronic limit order matching system as its core trading facility (''Matching System''), beginning in late 2006.[5] Under CHX's New Trading Model, Institutional Brokers were regarded as operating on the Exchange.[6] Recently, the Exchange amended its rules to provide that Institutional Brokers are no longer considered to be operating on the Exchange.[7] Given this change in the status of Institutional Brokers, the Exchange stated that the instant proposal is designed to enable Institutional Brokers to engage in business activities beyond those handled by IBRs, such as over-the-counter (''OTC'') market making, while ensuring that their activities as an Institutional Broker are appropriately governed by CHX rules.

The Exchange proposed to permit Institutional Brokers to operate a non-Institutional Broker unit within the same Participant Firm. A firm registered with the Exchange as Institutional Broker could maintain other lines of business separate and distinct from its Institutional Broker activities without subjecting those other areas to the requirements of Article 17, Rule 3 contingent upon the creation and maintenance of effective information barrier procedures as specified in proposed Rule 6 of Article 17. The Exchange stated that non-IBR activities of a Participant Firm registered as an Institutional Broker would remain subject to all other applicable provisions of the Exchange's rules.[8] The non-IBR personnel at an Institutional Broker could continue to send orders to the Exchange, but those orders would be regarded as standard order-sending Participant orders, not as Institutional Broker activity. The Exchange stated that it can and will distinguish between orders sent to the Matching System by IBRs and other orders sent by Institutional Brokers to the Matching System for billing and other purposes.[9]

CHX proposed to modify its rules correspondingly to redefine IBR[10] and ''Participant Firm,''[11] and amend the obligations of Institutional Brokers and IBRs.[12] Certain Institutional Broker privileges and responsibilities would apply only to the activities of those individuals registered with the Exchange as IBRs (and clerks thereto).[13] Further, the Exchange proposed to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 66177 (January 18, 2012), 77 FR 3527 (''Notice'').

[4] *See* CHX Rules, Article 17, Rule 1, Interpretation and Policy .02.

[5] *See* Securities Exchange Act Release No. 54550 (September 29, 2006), 71 FR 59563 (October 10, 2006) (SR–CHX–2006–05).

[6] *See id.*

[7] *See* Securities Exchange Act Release No. 65633 (October 26, 2011), 76 FR 67509 (November 1, 2011) (SR–CHX–2011–29).

[8] *See* Notice, 77 FR at 3529.

[9] *See id.*

[10] *See* Article 1, new Rule 1(gg) (defining IBR). *See also* amended Interpretation and Policy .02 to Article 17, Rule 1 (redefining IBR as an individual person affiliated with an Institutional Broker who is authorized to accept orders, enter bids and offers and execute transactions on behalf of an Institutional Broker and who has registered with the Exchange as an IBR as provided in Article 6).

[11] *See* Article 17, revised Rule 2 (clarifying that only Participants Firms are eligible to register as Institutional Brokers).

[12] *See* Article 17, Rule 3(e) (the obligations owed by Institutional Brokers under Article 11 include the affirmative obligation to provide electronic information to the Exchange in certain circumstances); Interpretation and Policy .01(a) to Article 6, Rule 3 (all applicants seeking to register as IBRs must successfully complete an Institutional Broker exam).

[13] *See* amended Article 17, Rule 3 (enumerated Institutional Broker responsibilities apply to activities by or through an affiliated IRR); amended Article 17, Rule 5(a) (the ability to make clearing submissions is limited to IBRs); new Article 17, Rule 6 (creating a duty of Institutional Brokers with a non-Institutional Broker unit to establish and maintain information barriers between the Institutional Broker unit and non-Institutional Broker unit); amended Article 17, Rule 1 (only registered IBRs are permitted to use Exchange systems provided for Institutional Brokers for handling orders and reporting transactions, *i.e.,* Brokerplex®). For a description of Brokerplex®, *see* Notice, 77 FR at 3528, n.9.

correct typographical mistakes and to make clarifying changes.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[14] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[15] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transaction in securities, to remove impediments and perfect the mechanisms of a free and open market, and, in general, to protect investors and the public interest.

As noted above, the Exchange recently amended its rules to provide that Institutional Brokers are no longer deemed to be operating on the Exchange.[16] Accordingly, Institutional Brokers are now permitted to handle and execute orders otherwise than on the Exchange.[17] Given this change, the Commission believes that it is appropriate and consistent with the Act for the Exchange to alter the privileges and responsibilities of Institutional Brokers to apply only to the activities of IBRs (and their clerks). The proposed changes would allow Institutional Brokers to carry out business strategies similar to those of other participants on the Exchange, while still ensuring that persons acting as IBRs are subject to the appropriate regulatory obligations. Further, the proposed rules regarding information barrier procedures should help ensure that there are adequate safeguards to prevent IBR units and non-IBR units from sharing non-public market information. As it gains experience overseeing the new multi-unit Institutional Brokers, the Commission expects the Exchange to assess whether any other informational barriers are necessary to prevent the flow of market information between IBR units and non-IBR units.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[18] that the proposed rule change (SR–CHX–2012–02) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–5474 Filed 3–6–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66501; File No. SR–BX–2012–014]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule To Amend the BOX LLC Agreement

March 1, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 22, 2012, NASDAQ OMX BX, Inc. (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the Sixth Amended and Restated Operating Agreement (''BOX LLC Agreement'') of the Boston Options Exchange Group LLC (''BOX LLC''), in connection with the proposed acquisition of TMX Group Inc., a company incorporated in Ontario, Canada (''TMX Group'') by Maple Group Acquisition Corporation, a company incorporated in Ontario, Canada (''Maple''). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://nasdaqomxbx.cchwallstreet.com/NASDAQOMXBX/Filings/.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 13, 2004, the Commission approved four Exchange proposals that together established, through an operating agreement among its owners, BOX LLC, a Delaware limited liability company, to operate BOX as an options trading facility of the Exchange.[5]

Currently, the Montreal Exchange Inc., a company incorporated in Quebec, Canada (''MX''), is a direct subsidiary of TMX Group. MX US 2, Inc., a Delaware corporation and indirect, wholly owned subsidiary of MX (''MX US''), holds a 53.83% ownership interest in BOX LLC.

The Exchange is submitting the proposed rule change to the Commission to amend the BOX LLC Agreement pursuant to the proposed Instrument of Accession in connection with the Acquisition (as defined below).

Maple's investors comprise Alberta Investment Management Corporation, Caisse de dépôt et placement du Québec, Canada Pension Plan Investment Board, CIBC World Markets Inc., Desjardins Financial Corporation, Dundee Capital Markets Inc., Fonds de solidarité des travailleurs du Québec (F.T.Q.), GMP Capital Inc., The Manufacturers Life Insurance Company, National Bank Financial & Co. Inc., Ontario Teachers' Pension Plan Board, Scotia Capital Inc. and TD Securities

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[14] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78f(b)(5).

[16] *See supra* note 7.

[17] *See id.*

[18] 15 U.S.C. 78s(b)(2).

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 49066 (January 13, 2004), 69 FR 2773 (January 20, 2004) (establishing a fee schedule for the proposed BOX facility); Securities Exchange Act Release No. 49065 (January 13, 2004), 69 FR 2768 (January 20, 2004) (creating Boston Options Exchange Regulation LLC to which the Exchange would delegate its self-regulatory functions with respect to the BOX facility); Securities Exchange Act Release No. 49068 (January 13, 2004), 69 FR 2775 (January 20, 2004) (approving trading rules for the BOX facility); Securities Exchange Act Release No. 49067 (January 13, 2004), 69 FR 2761 (January 20, 2004) (approving certain regulatory provisions of the operating agreement of BOX LLC).

Inc. (collectively, the ''Investors''). All of the Investors or their respective affiliates currently own common shares of Maple (the ''Maple Shares''). Each of the Investors currently owns less than 12% of Maple. The Maple Shares are currently privately held, not listed on any recognized exchange and not qualified for public distribution. However, after the completion of the second step of the Acquisition, the Maple Shares will be freely tradable (subject to 5-year contractual standstill arrangements to which some of the Investors have agreed to comply) and will be listed for trading on the Toronto Stock Exchange. Following the Acquisition, each of the Investors will own less than 9% of Maple and current shareholders of TMX Group will own at least 26% of Maple.

The Acquisition will be effected in two steps—(1) an offer (the ''Offer'') by Maple to the shareholders of TMX Group to exchange a minimum of 70% and a maximum of 80% of the outstanding common shares of TMX Group (''TMX Group Shares'') for cash, and (2) a subsequent transaction pursuant to a court-approved ''plan of arrangement'' [6] whereby TMX Group shareholders whose TMX Shares have not been acquired under the Offer will receive Maple Shares in exchange for their TMX Group Shares (the ''Subsequent Arrangement'', and collectively with the Offer, the ''Acquisition''). The Offer is set to expire on February 29, 2012, unless extended in accordance with the terms thereof, and subject to the terms and the conditions of the Offer, Maple will pay for TMX Group Shares validly deposited under the Offer and not properly withdrawn, ten days after the expiration of the Offer. If the Offer is successful, Maple will use its best efforts to complete the Subsequent Arrangement within 35 days after the expiration of the Offer.

As a result of the Acquisition, if successful, TMX Group will become a direct, wholly owned subsidiary of Maple. Consequently, MX US (including MX US's 53.83% ownership interest in BOX LLC) will become an indirect, wholly owned subsidiary of Maple. The Offer is subject to several conditions, including certain regulatory approvals, including, but not limited to, certain approvals from the Ontario Securities Commission, Autorité des marchés financiers (Québec), Alberta Securities Commission, British Columbia Securities Commission, Competition Bureau (Canada) and the Commission.

Maple has developed a preliminary business plan that it anticipates would be implemented upon completion of the Acquisition. The operations of each of MX and TMX Group will continue to be located in the same province in which it is currently located, and each will remain subject to its existing regulatory framework and oversight, including any changes to the recognition orders governing MX and TMX Group and additional undertakings that may be required by Canadian securities regulators as a condition of approving the Acquisition. MX US's management of its ownership interest in BOX will remain essentially unaffected by the Acquisition. Ownership of BOX through TMX Group, MX and MX US will not be affected by, and the ability of these entities to influence BOX will not change as a result of, the Acquisition.

Pursuant to Section 8.4(g) of the BOX LLC Agreement, as previously approved by the Commission, BOX LLC is required to amend the BOX LLC Agreement to make a Controlling Person [7] a party to the BOX LLC Agreement if such Controlling Person establishes a Controlling Interest [8] in any member of BOX LLC that, alone or together with any Affiliate [9] of such member of BOX LLC, holds a Percentage Interest [10] in BOX equal to or greater than 20%.[11] Therefore, since Maple is acquiring a Controlling Interest in TMX Group, whose wholly owned indirect subsidiary, MX US, owns a 53.83% ownership interest in BOX LLC, Maple, as a Controlling Person, is required to be, and will become, a party to the BOX LLC Agreement pursuant to the proposed Instrument of Accession. As a result, Maple will agree to abide by all the provisions of the BOX LLC Agreement, including those provisions requiring submission to the jurisdiction of the Commission.[12] The Exchange proposes to make this proposal operative upon the successful completion of the Offer, which is currently scheduled to expire on February 29, 2012.

For the reasons stated above, the Exchange is submitting to the Commission the proposed Instrument of Accession to the BOX LLC Agreement as a rule change.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(1),[14] in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Act, the rules and regulations thereunder, and the

[6] A ''plan of arrangement'' is a statutory procedure available under the *Business Corporations Act* (Ontario) as well as under the *Canada Business Corporations Act* and provincial corporations statutes. Where a corporation wishes to combine (or to make any other ''fundamental change'') but cannot achieve the result it wants under another section of the statute, it can apply to the court for an order approving a proposed ''plan of arrangement''.

[7] A ''Controlling Person'' is defined as ''a Person who, alone or together with any Affiliate of such Person, holds a controlling interest in a [BOX] Member.'' See Section 8.4(g)(v)(B), BOX LLC Agreement.

[8] A ''Controlling Interest'' is defined as ''the direct or indirect ownership of 25% or more of the total voting power of all equity securities of a Member (other than voting rights solely with respect to matters affecting the rights, preferences, or privileges of a particular class of equity securities), by any Person, alone or together with any Affiliate of such Person.'' See Section 8.4(g)(v)(A), BOX LLC Agreement.

[9] An ''Affiliate'' is defined as '', with respect to any Person, any other Person controlling, controlled by or under common control with, such Person. As used in this definition, the term ''control'' means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise with respect to such Person. A Person is presumed to control any other Person, if that Person: (i) Is a director, general partner, or officer exercising executive responsibility (or having similar status or performing similar functions); (ii) directly or indirectly has the right to vote 25 percent or more of a class of voting security or has the power to sell or direct the sale of 25 percent or more of a class of voting securities of the Person; or (iii) in the case of a partnership, has contributed, or has the right to receive upon dissolution, 25 percent or more of the capital of the partnership.'' See Section 1.1, BOX LLC Agreement.

[10] The ''Percentage Interest'' is defined as ''the ratio of the number of Units held by the Member to the total of all of the issued Units, expressed as a percentage and determined with respect to each class of Units, whenever applicable.'' See Section 1.1, BOX LLC Agreement.

[11] See Section 8.4(g), BOX LLC Agreement.

[12] The BOX LLC Agreement states, in part, that ''the Members, officers, directors, agents, and employees of Members irrevocably submit to the exclusive jurisdiction of the U.S. federal courts, U.S. Securities and Exchange Commission, and the Boston Stock Exchange, for the purposes of any suit, action or proceeding pursuant to U.S. federal securities laws, the rules or regulations thereunder, arising out of, or relating to, BOX activities or Article 19.6(a), (except that such jurisdictions shall also include Delaware for any such matter relating to the organization or internal affairs of BOX, provided that such matter is not related to trading on, or the regulation, of the BOX Market), and hereby waive, and agree not to assert by way of motion, as a defense or otherwise in any such suit, action or proceeding, any claims that they are not personally subject to the jurisdiction of the U.S. Securities and Exchange Commission, that the suit, action or proceeding is an inconvenient forum or that the venue of the suit, action or proceeding is improper, or that the subject matter hereof may not be enforced in or by such courts or agency.'' *See* BOX LLC Agreement, Section 19.6.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5) [sic].

rules of the Exchange. The Exchange also believes that this filing furthers the objectives of Section 6(b)(5) of the Act [15] in that it is designed to facilitate transactions in securities, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

Additionally, the Exchange notes that the provisions of the BOX LLC Agreement, previously approved by the Commission, provide a framework for addressing the Acquisition. Accordingly, the Exchange believes the Acquisition does not present any novel issues that have not been anticipated and addressed by the BOX LLC Agreement.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b-4(f)(6) thereunder.[17]

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the Acquisition does not present any novel issues that have not been anticipated and addressed by the BOX LLC Agreement. Therefore, the Commission designates the proposal operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2012–014 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2012–014. This file number should be included on the subject line if email is used.

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–BX–2012–014, and should be submitted on or before March 28, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

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[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66500; File No. SR–ICC–2012–01]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule To Provide That One Hundred Percent (100%) of the Initial Margin Requirement for Client-related Positions Cleared in a Clearing Participant's Customer Account Origin May Be Satisfied by a Clearing Participant Utilizing US Treasuries

March 1, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder [2] notice is hereby given that on February 17, 2012, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

ICC proposes rule amendments that will allow clearing participants to satisfy the initial margin-related liquidity requirements for client-related positions cleared in a clearing participant's customer account origin by posting US Treasuries.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule changes provide that one hundred percent (100%) of the initial margin requirement for client-related positions cleared in a clearing participant's customer account origin may be satisfied by the clearing participant utilizing US Treasuries.[4]

The ICC rules currently provide that for all accounts at least forty-five percent (45%) of initial margin must be posted in US dollar cash. The next twenty percent (20%) must be posted in US dollar cash or US Treasuries. The remaining thirty-five percent (35%) must be posted in US dollar cash or US Treasuries or G7 cash.

The proposed rules provide that at least sixty-five percent (65%) of the initial margin requirement for client-related positions cleared in a clearing participant's customer account origin must be posted in US dollar denominated assets (US dollar cash and/or US Treasuries) and the remaining thirty-five percent (35%) must be posted in US dollar cash or US Treasuries or G7 cash. Again, the proposed changes will apply only to the initial margin liquidity requirements associated with the initial margin requirement for client-related positions cleared in a clearing participant's customer account origin. The proposed changes will not apply to the ICC liquidity requirements for house initial margin and the guaranty fund.

The proposed rule changes are intended to facilitate client-related clearing. Customers of ICC's clearing participants have indicated that the current US dollar cash liquidity requirement is too restrictive and serves as a barrier to clearing. The proposed rule changes are consistent with the recently promulgated CFTC regulation 39.11(e)(1) that provides that the CFTC's ''cash'' liquidity requirement includes US Treasury obligations. ICC routinely monitors its potential liquidity needs and reevaluates its liquidity requirements to ensure that it has sufficient intraday liquidity to manage cash payments in the event of a member default.[5]

(B) Self-Regulatory Organization's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (A) By order approve or disapprove the proposed rule change or (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2012–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICC–2012–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICC and on ICC's Web site at *https://www.theice.com/publicdocs/regulatory_filings/ICEClearCredit_021712.pdf.*

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2012–01 and should

[3] The Commission has modified the text of the summaries prepared by ICC.

[4] ICC applies haircuts to US Treasuries to mitigate liquidity risk. The current haircuts are: 1.25% for US Treasuries maturing in less than one year, 2.5% for US Treasuries maturing in one to five years, 5.0% for US Treasuries maturing in five to ten years, and 10.0% for US Treasuries maturing in more than ten years (available at: *https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Collateral_Management.pdf*).

[5] Currently at least 45% of house initial margin and the guaranty fund requirements must be posted in US dollar cash and the ICC contribution to the guaranty fund is in US dollar cash. Additionally, ICC requires all members to meet and maintain their minimum guaranty fund requirement deposit of $20 million in US dollar cash regardless of the amount of each member's total guaranty fund requirement. In addition, in the event of immediate liquidity needs in the event of a member's default, ICC may borrow (through IntercontinentalExchange, Inc.) up to an aggregate principal amount of $100 million against IntercontinentalExchange, Inc.'s senior unsecured revolving credit facility.

be submitted on or before March 28, 2012.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[6]

Kevin O'Neill,

Deputy Secretary.

[FR Doc. 2012–5472 Filed 3–6–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66499; File No. SR–NASDAQ–2012–002]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Adopt an Alternative to the $4 Initial Listing Bid Price Requirement for the Nasdaq Capital Market of Either $2 or $3, if Certain Other Listing Requirements Are Met

March 1, 2012.

On January 3, 2012, The NASDAQ Stock Market LLC (''Exchange'' or ''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposal to adopt an alternative to the $4 minimum bid price initial listing requirement for the Nasdaq Capital Market of either $2 or $3, if certain other listing requirements are met. The proposed rule change was published for comment in the **Federal Register** on January 20, 2012.[3] The Commission received one comment on the proposal.[4]

Section 19(b)(2) of the Act[5] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is March 5, 2012.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period to take action on the proposed rule change so that it has sufficient time to consider the Exchange's proposal and the comment received. The Exchange's proposal would, among other things, allow a company's primary equity securities to be initially listed on the Nasdaq Capital Market if those securities have a minimum bid price of $2 or $3 per share and certain other listing requirements are met.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates April 19, 2012, as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–5471 Filed 3–6–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66498; File No. SR–CBOE–2012–020]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the CBOE Stock Exchange Fees Schedule

March 1, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 22, 2012, the Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the CBOE Stock Exchange (''CBSX'') Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend CBSX Maker and Taker fees for competitive and business purposes. First, CBSX proposes to increase the Maker fee for transactions in securities priced $1 or greater by $0.0001 per share, to $0.0018. CBSX also proposes to increase the Maker fee for transactions in securities priced $1 or greater executed by a market participant that adds two million or more shares of liquidity that day by $0.0001 per share, to $0.0016.

The Exchange also proposes to amend Maker and Taker fees for transactions in securities priced less than $1. The Exchange proposes to assess no Maker fee for such transactions in order to attract liquidity. The Exchange also proposes to increase the Taker fee for transactions in securities priced less than $1 to 0.30% of the dollar value of the transaction in order to normalize the Taker fee to equivalent offerings by other exchanges.[3]

The proposed changes are to take effect March 1, 2012.

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[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66159 (January 13, 2012), 77 FR 3021.

[4] *See* Letter from David A. Donohoe, Jr., Donohoe Advisory Associates LLC, to Elizabeth M. Murphy, Secretary, Commission, dated February 10, 2012.

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Chicago Stock Exchange, Inc. Fee Schedule, Section E(1).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[4] Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[5] which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities. The slight increases to the Maker fees for transactions in securities priced $1 or greater are reasonable because the amount of the increase is minimal, and the amounts of the fees are within the range of Maker fees that have been assessed previously. The slight increases to the Maker fees for transactions in securities priced $1 or greater are equitable and not unfairly discriminatory because the fees will be assessed to all market participants equally.

The change to eliminate the Maker for transactions in securities priced less than $1 fee is reasonable because it will allow market participants to no longer have to pay a Maker fee for such transactions. This change is equitable and not unfairly discriminatory because it will allow all market participants to avoid paying such a fee. The change to increase the Taker fee for transactions in securities priced less than $1 is reasonable because the new amount of the fee is within the range of fees for similar transactions at other exchanges,[6] and is equitable and not unfairly discriminatory because it will be assessed to all market participants equally.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4).

[6] *See* footnote 1.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is designated by the Exchange as establishing or changing a due, fee, or other charge, thereby qualifying for effectiveness on filing pursuant to Section 19(b)(3)(A) of the Act[7] and subparagraph (f)(2) of Rule 19b–4[8] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2012–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2012–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CBOE–2012–020 and should be submitted on or before March 28, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–5470 Filed 3–6–12; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 C.F.R. 240.19b–4(f)(2).

[9] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act (PRA) of 1995, effective October 1, 1995. This notice includes an extension and two revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB)

Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA)

Social Security Administration, DCRDP, Attn: Reports Clearance Officer, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–

966–2830, Email address: *OPLM.RCO@ssa.gov.*

The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than May 7, 2012. Individuals can obtain copies of the collection instruments by calling the SSA Reports Clearance Officer at 410–965–8783 or by writing to the above email address.

1. *Testimony by Employees and the Production of Records and Information in Legal Proceedings—20 CFR 403.100–.155—0960–0619.* Regulations at 20 CFR 403.100–.155 of the Code of Federal Regulations establish SSA's policies and procedures for an individual, organization, or government entity to request official agency information, records, or testimony of an agency employee in a legal proceeding when the agency is not a party. The request, which respondents submit in writing to the Commissioner, must (1) fully set out the nature and relevance of the sought testimony; (2) explain why the information is not available by other means; (3) explain why it is in SSA's interest to provide the testimony; and (4) provide the date, time, and place for the testimony. Respondents are individuals or entities who request testimony from SSA employees in connection with a legal proceeding.

Type of Request: Extension of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
20 CFR 403.100–403.155	100	1	60	100

2. *Identifying Information for Possible Direct Payment of Authorized Fees—0960–0730.* SSA collects information from claimants' appointed representatives on Form SSA–1695 to (1) process and facilitate direct payment of authorized fees; (2) issue a Form 1099–MISC, if applicable; and (3) establish a link between each claim for benefits and the data we collect on the SSA–1699 for our appointed representative database. The respondents are attorneys and other individuals who represent claimants for benefits before SSA.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1695	10,000	40	10	66,667

3. *Electronic Records Express—0960–0753.* Electronic Records Express (ERE) is a web-based SSA program that allows medical providers to electronically submit disability claimant data to SSA. Both medical providers and other third parties with connections to disability applicants or recipients can use this system. This collection comprises user enrollment in ERE; other OMB-approved collections include the actual submission of information electronically. The respondents are medical providers who evaluate or treat disability claimants or recipients and are ERE users.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
ERE	3,552,176	1	10	592,029

Dated: March 2, 2012.

Faye Lipsky,

Reports Clearance Director, Office of Regulations and Reports Clearance, Social Security Administration.

[FR Doc. 2012–5573 Filed 3–6–12; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending February 18, 2012

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2006–25857.

Date Filed: February 16, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: March 8, 2012.

Description: Application of Sundance Air Venezuela S.A. requesting renewal of its existing foreign air carrier permit

authorizing it to engage in the foreign air transportation of property and mail between points in Venezuela and points in the United States.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–5526 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending February 18, 2012

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: DOT–OST–2012–0024.

Date Filed: February 16, 2012.

Parties: Members of the International Air Transport Association.

Subject: PTC COMP Mail Vote 701—Resolution 011a Mileage Manual, Non TC Member/Non IATA Carrier Sectors, Intended Effective Date 15 March 2012, for Implementation 1 April 2012 (Memo 1663).

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–5523 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Government/Industry Aeronautical Charting Forum Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces the bi-annual meeting of the Federal Aviation Administration (FAA) Aeronautical Charting Forum (ACF) to discuss informational content and design of aeronautical charts and related products, as well as instrument flight procedures development policy and design criteria.

DATES: The ACF is separated into two distinct groups. The Instrument Procedures Group (IPG) will meet April 24, 2012 from 8:30 a.m. to 5 p.m. The Charting Group will meet April 25 and 26, 2012 from 8:30 a.m. to 5 p.m.

ADDRESSES: The meeting will be hosted by Innovative Solutions International, a Pragmatics, Inc. Company at 1761 Business Center Drive, Reston, VA 20190.

FOR FURTHER INFORMATION CONTACT: For information relating to the Instrument Procedures Group, contact Thomas E. Schneider, FAA, Flight Procedures Standards Branch, AFS–420, 6500 South MacArthur Blvd., P.O. Box 25082, Oklahoma City, OK 73125; telephone (405) 954–5852; fax: (405) 954–2528.

For information relating to the Charting Group, contact Valerie S. Watson, FAA, National Aeronautical Navigation Products (AeroNav Products), Quality Assurance & Regulatory Support, AJV–3B, 1305 East-West Highway, SSMC4, Station 4640, Silver Spring, MD 20910; telephone: (301) 427–5155, fax: (301) 427–5412.

The public must make arrangements by April 6, 2012, to present oral statements at the meeting. The public may present written statements and/or new agenda items to the committee by providing a copy to the person listed in the **FOR FURTHER INFORMATION CONTACT** section not later than April 6, 2012, Public statements will only be considered if time permits.

Issued in Washington, DC, on February 28, 2012.

Valerie S. Watson,

Co-Chair, Aeronautical Charting Forum.

[FR Doc. 2012–5293 Filed 3–6–12; 8:45 am]

BILLING CODE M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Alaska Federal Lands Long Range Transportation Plan

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of extension of comment period.

SUMMARY: On December 12, 2011, via a **Federal Register** notice, we the Federal Highway Administration, along with the Bureau of Land Management, Fish and Wildlife Service, Forest Service and National Park Service, announced the availability of the draft Alaska Federal Lands Long Range Transportation Plans (LRTP) for public review and comment.

The draft plans outline a strategy for a multi-agency approach to improving and maintaining transportation assets that provide access to Federal Lands in the Alaska region over the next 20 years. We requested comments be submitted by March 12, 2012. With this notice, we extend that comment period from 90 days to 120 days.

DATES: Please provide your comments by April 11, 2012.

FOR FURTHER INFORMATION CONTACT: Federal Highway Administration (FHWA), DOT: Roxanne Bash, (360) 619–7558.

Bureau of Land Management (BLM), DOI: Randy Goodwin, (907) 474–2369.

Fish and Wildlife Service (FWS), DOI: Helen Clough, (907) 786–3353.

Forest Service (FS), USDA: Marie Messing, (907) 586–8834.

National Park Service (NPS), DOI: Paul Schrooten, (907) 644–3388.

SUPPLEMENTARY INFORMATION: On December 12, 2011, at 76 FR 77300, the FHWA published a notice in the **Federal Register** inviting comments to the Alaska Federal Lands draft Long Range Transportation Plans. The draft Plans are available on our project Web site: *http://www.akfedlandslrtp.org.* Submit comments for any or all plans electronically through the NPS Planning, Environment and Public Comment system at *http://parkplanning.nps.gov.* The original deadline for comments was March 12, 2012. This notice extends the deadline by 30 calendar days to April 11, 2012. Further information can be found in the December 12, 2011, notice.

Authority: 23 U.S.C. 204.

Dated: February 27, 2012.

Clara H. Conner,

Division Engineer, Western Federal Lands Highway Division, FHWA, Vancouver, Washington.

[FR Doc. 2012–5224 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–36–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice To Rescind a Notice of Intent To Prepare an Environmental Impact Statement: Highway US–30, Schuyler to Fremont Colfax and Dodge Counties, NE

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice to rescind a Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that the Notice of Intent (NOI) for the preparation of an Environmental Impact Statement for the US Highway 30, Schuyler to Fremont project in Colfax

and Dodge Counties, Nebraska, is being rescinded. The NOI was published in the **Federal Register** on August 29, 2005. This rescission is based on the desire of the Nebraska Department of Roads to fund the project entirely with newly acquired state funds. NDOR plans to have the improvements completed with state funds in the FY 2016–2019 timeframe.

FOR FURTHER INFORMATION CONTACT: Melissa Maiefski, Program Delivery Team Lead, FHWA, Nebraska Division, 100 Centennial Mall North, Room 220, Lincoln, Nebraska 68508, Telephone: (402)742–8473.

SUPPLEMENTARY INFORMATION: On August 29, 2005, FHWA and NDOR announced their intent to prepare an EIS pursuant to 40 CFR 1508.22 for the proposed improvements along a 26-mile segment of US–30, from Schuyler, Nebraska to Fremont, Nebraska. In an effort to develop a preliminary purpose and need statement and a reasonable range of alternatives, the NDOR convened a local public interest advisory group in 2005, which was comprised of residents, stakeholders, and local officials from the study area. In December 2006, the advisory group prepared a majority and a minority recommendation for a locally preferred solution, along with other reasonable alternatives. This recommendation was to be considered in the development of the range of alternatives to be studied in the EIS. After completion of the advisory group's work, NDOR reviewed the Statewide Transportation Improvement Program (STIP) and determined that funding for construction of the project was not likely to be available for the foreseeable future; therefore, the environmental process was halted until a financial plan could be identified. In 2009, the United States Army Corps of Engineers (USACE) began public meetings related to a Section 205 study of flood protection measures for the City of Fremont that included alternatives in the US–30 corridor. Although funding for construction of US–30 improvements was still uncertain, NDOR and FHWA determined that it would be beneficial for the US–30 environmental process to resume, coordinated with the USACE improvements. In 2011, NDOR was beginning to draft a Coordination Plan in accordance with Section 6002 of SAFETEA–LU to outline the process of agency and public participation during the environmental review process, when the Nebraska State Legislature enacted LB84, legislation which will divert ¼ cent of the sales tax revenue for road construction projects for the next 20 years, beginning in 2013. NDOR has requested to rescind the Notice of Intent to Prepare an EIS due to the enactment of LB84 and the resulting availability of state funds to deliver this project. Further, NDOR will continue to coordinate closely with appropriate agencies, seek public involvement, and undergo environmental evaluations pursuant to their State environmental process. Comments or questions concerning the rescission of this proposed action and the EIS should be directed to the FHWA at the address provided above.

Authority: 23 U.S.C. 315; 49 CFR 1.48.

Dated: February 28, 2012.

Joseph A. Werning,

Division Administrator, Nebraska.

[FR Doc. 2012–5462 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0032]

Commercial Driver's License Standards: Application for Exemption; Daimler Trucks North America (Daimler)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Daimler Trucks North America (Daimler) has applied for two drivers of commercial motor vehicles (CMVs) to be exempt from the Federal requirement to hold a commercial driver's license (CDL) issued by one of the States. Daimler requests that the exemption cover two German project engineers who will test-drive CMVs for Daimler within the United States. Daimler states the exemption is needed to meet future vehicle safety and environmental regulatory requirements and to promote the development of technology advancements in vehicle safety systems and emissions reductions. These Daimler drivers hold valid German CDLs and need to be able to test-drive Daimler vehicles on U.S. roads to better understand product requirements for these systems in ''real world'' environments in the U.S. market, and verify results. Daimler believes the requirements for a German CDL are such that they ensure that the same level of safety is met or exceeded as if these drivers had U.S. state-issued CDLs.

DATES: Comments must be received on or before April 6, 2012.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2012–0032 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* In the ENTER KEYWORD OR ID box enter FMCSA–2012–0032 and click on the tab labeled SEARCH. On the ensuing page, click on any tab labeled SUBMIT A COMMENT on the extreme right of the page and a page should open that is titled ''Submit a Comment.'' You may identify yourself under section 1, ENTER INFORMATION or you may skip section 1 and remain anonymous. You enter your comments in section 2, TYPE COMMENT & UPLOAD FILE. When you are ready to submit your comments, click on the tab labeled SUBMIT. Your comment is then submitted to the docket; and you will receive a tracking number.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the Public Participation heading below. Note that all comments received will be posted without change to *www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov* at any time, and in the ENTER KEYWORD OR ID box enter FMCSA–2012–0032 and click on the tab labeled SEARCH.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the U.S. Department of Transportation's online privacy policy at *www.dot.gov/privacy* or the complete Privacy Act Statement in the **Federal Register** published on December 29, 2010 (75 FR 82133).

Public Participation: The *www.regulations.gov* Web site is generally available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the ''help'' section of the *www.regulations.gov* web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Yager, Chief, FMCSA Driver and Carrier Operations Division; Office of Bus and Truck Standards and Operations; Telephone: 202–366–4325. Email: *MCPSD@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for denying or, in the alternative, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 2 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

Request for Exemption

Daimler has applied for an exemption for from the commercial driver's license (CDL) rules, specifically 49 CFR 383.23 that prescribes licensing requirements for drivers operating commercial motor vehicles (CMVs) in interstate or intrastate commerce. Daimler requests the exemption because these drivers are citizens of Germany, and therefore cannot apply for a CDL in any of the U.S. States. A copy of the application is in Docket No. FMCSA–2012–0032.

The exemption would allow two drivers to operate CMVs in interstate commerce to support Daimler field tests to meet future vehicle safety and environmental regulatory requirements and to promote the development of technology advancements in vehicle safety systems and emissions reductions. According to Daimler, the drivers will typically drive for no more than 6 hours per day for 2 consecutive days, and that 10 percent of the test driving will be on two-lane state highways, while 90 percent will be on interstate highways. The driving for each driver will consist of no more than 200 miles per day, for a total of 400 miles during a two-day period on a quarterly basis.

The drivers are Georg Weiberg and Klaus-Dieter Holloh, and Daimler requests that the exemption cover a two-year period. The drivers hold valid German CDLs, and as explained by Daimler in its exemption requests, the requirements for a German CDL are such that they ensure that the same level of safety is met or exceeded as if these drivers had U.S. State-issued CDLs.

FMCSA has determined the process for obtaining a German-issued CDL is comparable to, or as effective as the Federal requirements of Part 383, and adequately assesses each driver's ability to operate CMVs in the United States.

Request for Comments

In accordance with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA requests public comment on Daimler's application for an exemption from the CDL requirements of 49 CFR 383.23. The Agency will consider all comments received by close of business on April 6, 2012. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: February 29, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–5521 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2011–0368]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt twenty individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions will enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions are effective March 7, 2012. The exemptions expire on March 7, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

Background

On January 24, 2012, FMCSA published a notice of receipt of Federal

diabetes exemption applications from twenty individuals and requested comments from the public (77 FR 3549). The public comment period closed on February 23, 2012 and no comments were received.

FMCSA has evaluated the eligibility of the twenty applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These twenty applicants have had ITDM over a range of 1 to 39 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the January 24, 2012, **Federal Register** notice and they will not be repeated in this notice.

Discussion of Comment

FMCSA did not receive any comments in this proceeding.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Conclusion

Based upon its evaluation of the twenty exemption applications, FMCSA exempts, Guillermo V. Apodaca (NM), Charles S. Bird (VA), Dorin D. Blodgett (IN), James W. Dusing (MN), Jeffrey M. Halida (WS), Matthew E. Hay (TX), Tracy N. Jenkins (DE), Jon W. Jernigan (OK), Gregory A. King (NC), Derrick D. LaRue (RI), Matthew R. Linehan (NY), David J. Lloyd (AL), Cory A. Meadows (OH), Lori L. Monosso (WS), Kenneth D. Nemetz (WS), John L. Scherette (WA), James P. Shurkus (NH), Joel L. Topping (NV), Joshua C. Wyse (OH) and Rowland P. Yee (HI) from the ITDM requirement in 49 CFR 391.41(b)(3), subject to the conditions listed under ''Conditions and Requirements'' above.

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption will be valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: February 28, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–5517 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0383]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemption from the diabetes mellitus requirement; request for comments.

SUMMARY: FMCSA announces receipt of applications from 17 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with

ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before April 6, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0383 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 17 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by the statutes.

Qualifications of Applicants

Alvin Acevedo

Mr. Acevedo, 33, has had ITDM since 1996. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Acevedo understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Acevedo meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Jerry D. Baughn

Mr. Baughn, 58, has had ITDM since 2007. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Baughn understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Baughn meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Bobby D. Bennett

Mr. Bennett, 33, has had ITDM since 2004. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bennett understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bennett meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Georgia.

Mark S. Clemence

Mr. Clemence, 50, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Clemence understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Clemence meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Larry G. Foley

Mr. Foley, 56, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Foley understands

diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Foley meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from West Virginia.

Elwood F. Gorom

Mr. Gorom, 72, has had ITDM since 2009. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gorom understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gorom meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Larry A. Grizzel

Mr. Grizzel, 65, has had ITDM since 2007. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Grizzel understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Grizzel meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Mike W. Holland

Mr. Holland, 57, has had ITDM since 2001. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Holland understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Holland meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Steven M. Lewis, Sr.

Mr. Lewis, 48, has had ITDM since 2005. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lewis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lewis meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from North Carolina.

Dan M. McAllister

Mr. McAllister, 40, has had ITDM since 2005. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McAllister understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McAllister meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class B operator's license from Wisconsin.

Meredith M. McCabe

Ms. McCabe, 55, has had ITDM since 2006. Her endocrinologist examined her in 2011 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. McCabe that she understands diabetes management and monitoring, has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. McCabe meets the vision requirements of 49 CFR 391.41(b)(10). Her ophthalmologist examined her in 2011 and certified that she does not have diabetic retinopathy. She holds a Class C operator's license from Georgia.

Paul F. Rivers

Mr. Rivers, 54, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rivers understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rivers meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Marcus V. Romo

Mr. Romo, 37, has had ITDM since 2004. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Romo understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Romo meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Idaho.

Gary L. Siverson

Mr. Siverson, 69, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in

the last 5 years. His endocrinologist certifies that Mr. Siverson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Siverson meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from North Dakota.

Wayne L. Snyder

Mr. Snyder, 54, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Snyder understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Snyder meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

William F. Watkins, Jr.

Mr. Watkins, 68, has had ITDM since 2003. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Watkins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Watkins meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class C operator's license from Pennsylvania.

Justin K. Zimmerschied

Mr. Zimmerschied, 21, has had ITDM since 2002. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Zimmerschied understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Zimmerschied meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

Issued on: February 28, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–5518 Filed 3–6–12; 8:45 am]

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[1] Section 4129(a) refers to the 2003 notice as a ''final rule.'' However, the 2003 notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2003–16564; FMCSA–2007–0071]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 20 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective March 31, 2012. Comments must be received on or before April 6, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: FMCSA–2003–16564; FMCSA–2007–0071, using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5

p.m., Monday through Friday, except Federal Holidays.

• *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 20 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 20 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Alberto Blanco (NC)
Michael B. Canedy (MN)
Cary Carn (NJ)
Larry A. Cossin (OH)
Charles W. Cox (
Gary W. Ellis (NC)
Dennis J. Evers (OK)
Hector O. Flores (MD)
Miguel Godinez (CA)
W. Roger Goold (AZ)
K. Lee Guse (OH)
Steven E. Halsey (MO)
John C. Hendricks (OH)
Thomas M. Leadbitter (PA)
John L. Lewis (OK)
Jonathan P. Lovel (IL)
Tom A. McCarty (NM)
Kent S. Reining (IL)
Enrique G. Salinas, Jr. (TX)
Richard Wylie (CT)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 20 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (68 FR 74699; 69 FR 10503; 71 FR 6829; 73 FR 6242; 73 FR 16950; 73 FR 8392; 74 FR 65842; 75 FR 9477; 75 FR 9478). Each of these 20 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by April 6, 2012.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 20 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: February 28, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–5519 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0365]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt thirteen individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective March 7, 2012. The exemptions expire on March 7, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

Background

On January 24, 2012, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (77 FR 3552). That notice listed thirteen applicants' case histories. The thirteen individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the thirteen applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The thirteen exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including prosthesis, macular scar, amblyopia, congenial optic atrophy, ocular hypertension, retinal detachment, cataracts and corneal scaring. In most cases, their eye conditions were not recently developed. Eight of the applicants were either born with their vision impairments or have had them since childhood. The five individuals that sustained their vision conditions as adults and have had them for a period of 3 to 35 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these thirteen drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 3 to 44 years. In the past 3 years, none of the drivers were involved in crashes, and none were convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the January 24, 2012 notice (77 FR 3552).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA's) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the thirteen applicants, none of the drivers were involved in a crash and none were convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the thirteen applicants listed in the notice of January 24, 2012 (77 FR 3552).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the thirteen individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following:

(1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received no comments in this proceeding.

Conclusion

Based upon its evaluation of the thirteen exemption applications, FMCSA exempts Daniel C. Berry (AR), Jeffery H. Bohr (IA), William J. Byron (NC), Michael P. Callihan (OH), John Edmondson (AL), Richard P. Frederiksen (WY), Stephen J. Hall (WA), Lonnie B. Hicks, Jr. (OK), Samuel V. Holder (IL), Timothy L. Klompien (MT), Jerry L. Pettijohn (OK), Jake Richter (KS) and Bradley S. Sanders (NM) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: February 28, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–5520 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2012 0029]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intentions to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before May 7, 2012.

FOR FURTHER INFORMATION CONTACT: Rita Jackson, Office of Maritime Workforce Development, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: 202–366–0284; or email: *rita.jackson@dot.gov.* Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Maritime Administration Service Obligation Compliance Annual Report (Formerly, Service Obligation Compliance Report and Merchant Marine Reserve/U.S. Naval Reserve Annual Report).

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0509.

Form Numbers: MA–930.

Expiration Date of Approval: Three years after date of approval by the Office of Management and Budget.

Summary of Collection of Information: The Maritime Education and Training Act of 1980, imposes a service obligation on every graduate of the U.S. Merchant Marine Academy and every subsidized State maritime academy graduate who received a student incentive payment. This mandatory service obligation is for the Federal financial assistance the graduate received as a student. In addition, this obligation requires the graduate to maintain a license as an officer in the merchant marine and to report annually on reserve status, training and employment.

Need and Use of the Information: The information collection is necessary to determine if a graduate of the U.S. Merchant Marine Academy or subsidized State maritime academy graduate is complying with the terms of the service obligation.

Description of Respondents: Graduates of the U.S. Merchant Marine Academy and every subsidized State maritime academy graduate who received a student incentive payment.

Annual Responses: 1400.

Annual Burden: 467 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. Comments also may be submitted by electronic means via the Internet at *http://www.regulations.gov.* Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT (or EST), Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at *http://www.regulations.gov.*

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://www.regulations.gov.*

Authority: 49 CFR 1.66.

Dated: March 1, 2012.

By Order of the Maritime Administrator.

Julie Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5527 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2012–0020]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel UNCLE SAM; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0020. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel UNCLE SAM is:

Intended Commercial Use of Vessel: ''Sailing tours, day charters, and

instruction. Private charters based out of San Juan Bay, Puerto Rico, with tourists as primary customers. Short sailing excursions generally lasting 2 hours.''

Geographic Region: ''Puerto Rico.''

The complete application is given in DOT docket MARAD–2012–0020 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: February 27, 2012.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5485 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2012–0027]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel AURORA B; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0027. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel AURORA B is:

Intended Commercial Use of Vessel: ''Will provide special chartering options including services to ''Make A Wish'' type organizations and at sea memorial services, as well as a research platform for small marine university research projects and small developers of marine technology in the area.''

Geographic Region: ''Maine, Massachusetts, Rhode Island.''

The complete application is given in DOT docket MARAD–2012–0027 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

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Dated: March 1, 2012.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5502 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2012 0025]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CHANGING CHANNELS; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0025. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents

entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CHANGING CHANNELS is:

Intended Commercial Use of Vessel: ''The vessel is a 38-foot sailing catamaran owned by our sailing club. The vessel will be used for teaching sailing classes and for sailboat charters in San Diego and Long Beach. Our sailing club owns a fleet of sailboats used to teach sailing classes from Basic Keelboat Sailing through Bareboat Cruising, with all sailing classes being certified through U.S. Sailing. A waiver will allow us to teach group sailing lessons on the catamarans.''

Geographic Region: ''California.''

The complete application is given in DOT docket MARAD–2012–0025 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

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Dated: March 1, 2012.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5491 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2012]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel IN THE SHELTER; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0024. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel IN THE SHELTER is:

Intended Commercial Use of Vessel: ''The vessel is a 38 foot sailing catamaran owned by our sailing club. The vessel will be used for teaching sailing lessons and for sailboat charters in San Diego and Long Beach. Our sailing club owns a fleet of sailboats used to teach sailing classes from Basic Keelboat through Bareboat Cruising, with all sailing classes being certified through US Sailing. A waiver will allow us to teach group sailing lessons on the catamarans.''

Geographic Region: ''California.''

The complete application is given in DOT docket MARAD–2012–0024 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

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Dated: March 1, 2012.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5489 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2012–0021]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ROYALISTE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0021. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ROYALISTE is:

Intended Commercial Use of Vessel: ''Moored dockside attraction vessel and occasional sail training vessel for 6 or fewer passengers.''

Geographic Region: ''Oregon and Washington.''

The complete application is given in DOT docket MARAD–2012–0021 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: February 27, 2012.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5483 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2012–0026]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SIREN; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 6, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0026. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W21–203, Washington, DC 20590. Telephone 202–366–5979, Email *Joann.Spittle@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SIREN is:

Intended Commercial Use Of Vessel: ''Sailing charters.''

Geographic Region: ''California.''

The complete application is given in DOT docket MARAD–2012–0026 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: March 1, 2012.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–5500 Filed 3–6–12; 8:45 am]

BILLING CODE 4910–81–P

FEDERAL REGISTER

Vol. 77 Wednesday,
No. 45 March 7, 2012

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495
Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

[CMS–0044–P]

RIN 0938–AQ84

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would specify the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments. In addition, it would specify payment adjustments under Medicare for covered professional services and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of certified EHR technology and other program participation requirements. This proposed rule would also revise certain Stage 1 criteria, as well as criteria that apply regardless of Stage, as finalized in the final rule titled Medicare and Medicaid Programs; Electronic Health Record Incentive Program published on July 28, 2010 in the **Federal Register**. The provisions included in the Medicaid section of this proposed rule (which relate to calculations of patient volume and hospital eligibility) would take effect shortly after finalization of this rule, not subject to the proposed 1 year delay for Stage 2 of meaningful use of certified EHR technology. Changes to Stage 1 of meaningful use would take effect for 2013, but most would be optional until 2014.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 7, 2012.

ADDRESSES: In commenting, please refer to file code CMS–0044–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0044–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0044–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Elizabeth Holland, (410) 786–1309, or Robert Anthony, (410) 786–6183, EHR Incentive Program issues. Jessica Kahn, (410) 786–9361, for Medicaid Incentive Program issues. James Slade, (410) 786–1073, or Matthew Guerand, (410) 786–1450, for Medicare Advantage issues. Travis Broome, (214) 767–4450, Medicare payment adjustment issues. Douglas Brown, (410) 786–0028, or Maria Durham, (410) 786–6978, for Clinical quality measures issues. Lawrence Clark, (410) 786–5081, for Administrative appeals process issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

ARRA—American Recovery and Reinvestment Act of 2009
AAC—Average Allowable Cost (of certified EHR technology)
AIU—Adopt, Implement, Upgrade (certified EHR technology)
CAH—Critical Access Hospital
CAHPS—Consumer Assessment of Healthcare Providers and Systems
CCN—CMS Certification Number
CFR—Code of Federal Regulations
CHIP—Children's Health Insurance Program
CHIPRA—Children's Health Insurance Program Reauthorization Act of 2009
CMS—Centers for Medicare & Medicaid Services
CPOE—Computerized Physician Order Entry
CY—Calendar Year
EHR—Electronic Health Record
EP—Eligible Professional
EPO—Exclusive Provider Organization
FACA—Federal Advisory Committee Act
FFP—Federal Financial Participation
FFY—Federal Fiscal Year
FFS—Fee-For-Service
FQHC—Federally Qualified Health Center
FTE—Full-Time Equivalent
FY—Fiscal Year
HEDIS—Healthcare Effectiveness Data and Information Set
HHS—Department of Health and Human Services
HIE—Health Information Exchange
HIT—Health Information Technology
HITPC—Health Information Technology Policy Committee
HIPAA—Health Insurance Portability and Accountability Act of 1996

HITECH—Health Information Technology for Economic and Clinical Health Act
HMO—Health Maintenance Organization
HOS—Health Outcomes Survey
HPSA—Health Professional Shortage Area
HRSA—Health Resource and Services Administration
IAPD—Implementation Advance Planning Document
ICR—Information Collection Requirement
IHS—Indian Health Service
IPA—Independent Practice Association
IT—Information Technology
MA—Medicare Advantage
MAC—Medicare Administrative Contractor
MAO—Medicare Advantage Organization
MCO—Managed Care Organization
MITA—Medicaid Information Technology Architecture
MMIS—Medicaid Management Information Systems
MSA—Medical Savings Account
NAAC—Net Average Allowable Cost (of certified EHR technology)
NCQA—National Committee for Quality Assurance
NCVHS—National Committee on Vital and Health Statistics
NPI—National Provider Identifier
NPRM—Notice of Proposed Rulemaking
ONC—Office of the National Coordinator for Health Information Technology
PAHP—Prepaid Ambulatory Health Plan
PAPD—Planning Advance Planning Document
PFFS—Private Fee-For-Service
PHO—Physician Hospital Organization
PHS—Public Health Service
PHSA—Public Health Service Act
PIHP—Prepaid Inpatient Health Plan
POS—Place of Service
PPO—Preferred Provider Organization
PQRI—Physician Quality Reporting Initiative
PSO—Provider Sponsored Organization
RHC—Rural Health Clinic
RPPO—Regional Preferred Provider Organization
SAMHSA—Substance Abuse and Mental Health Services Administration
SMHP—State Medicaid Health Information Technology Plan
TIN—Tax Identification Number

Table of Contents

I. Executive Summary and Overview

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for the Regulatory Action

In this proposed rule the Secretary of the Department of Health and Human Services (the Secretary) would specify Stage 2 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, as well as introduce changes to the program timeline and detail payment adjustments. These proposed criteria were substantially adopted from the recommendations of the Health IT Policy Committee (HITPC), a Federal Advisory Committee that coordinates industry and provider input regarding the Medicare and Medicaid EHR Incentive Programs, as well as in consideration of current program data for the Medicare and Medicaid EHR Incentive Programs.

b. Legal Authority for the Regulatory Action

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology.

Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, Medicare Advantage (MA) organizations (for certain qualifying EPs and hospitals that meaningfully use certified EHR technology), subsection (d) hospitals and critical access hospitals (CAHs) respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals and CAHs that are not meaningful users of certified EHR technology for certain associated reporting periods.

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments. (There are no payment adjustments under Medicaid). For a more detailed explanation of statutory basis, see the Stage 1 final rule (75 FR 44316 through 44317).

2. Summary of Major Provisions

a. Stage 2 Meaningful Use Objectives and Measures

In the Stage 1 final rule we outlined Stage 1 criteria, we finalized a separate set of core objectives and menu objectives for both EPs and eligible hospitals and CAHs. EPs and hospitals must meet or qualify for an exclusion to all of the core objectives and 5 out of the 10 menu measures in order to qualify for an EHR incentive payment. In this proposed rule, we propose to maintain the same core-menu structure for the program for Stage 2. We propose that EPs must meet or qualify for an exclusion to 17 core objectives and 3 of 5 menu objectives. We propose that eligible hospitals and CAHs must meet or qualify for an exclusion to 16 core objectives and 2 of 4 menu objectives. Nearly all of the Stage 1 core and menu objectives would be retained for Stage 2. The ''exchange of key clinical information'' core objective from Stage 1 would be re-evaluated in favor of a more robust ''transitions of care'' core objective in Stage 2, and the ''Provide patients with an electronic copy of their health information'' objective would be removed because it would be replaced by an ''electronic/online access'' core objective. There are also multiple Stage 1 objectives that would be combined into more unified Stage 2 objectives, with a subsequent rise in the measure threshold that providers must achieve for each objective that has been retained from Stage 1.

b. Reporting on Clinical Quality Measures (CQMs)

EPs, eligible hospitals, and CAHs are required to report on specified clinical quality measures in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs. For EPs, we propose a set of clinical quality measures beginning in 2014 that align with existing quality programs such as measures used for the Physician Quality Reporting System (PQRS), CMS Shared Savings Program, and National Council for Quality Assurance (NCQA) for medical home accreditation, as well as those proposed under Children's Health Insurance Program Reauthorization Act (CHIPRA) and under ACA Section 2701. For eligible hospitals and CAHs, the set of CQMs we propose beginning in 2014 would align with the Hospital Inpatient Quality Reporting (HIQR) and the Joint Commission's hospital quality measures.

This proposed rule also outlines a process by which EPs, eligible hospitals, and CAHs would submit CQM data electronically, reducing the associated burden of reporting on quality measures for providers. We are soliciting public feedback on several mechanisms for electronic CQM reporting, including aggregate-level electronic reporting group reporting options; and through existing quality reporting systems. Within these mechanisms of reporting, we outline different approaches to CQM reporting that would require EPs to report 12 CQMs and eligible hospitals and CAHs to report 24 CQMs in total.

c. Payment Adjustments and Exceptions

Medicare payment adjustments are required by statute to take effect in 2015. We propose a process by which payment adjustment would be determined by a prior reporting period. Therefore, we propose that any successful meaningful user in 2013

would avoid payment adjustment in 2015. Also, any Medicare provider that first meets meaningful use in 2014 would avoid the penalty if they are able to demonstrate meaningful use at least 3 months prior to the end of the calendar or fiscal year (respectively) and meet the registration and attestation requirement by July 1, 2014 (eligible hospitals) or October 1, 2014 (EPs).

We also propose exceptions to these payment adjustments. This proposed rule outlines three categories of exceptions based on the lack of availability of Internet access or barriers to obtaining IT infrastructure, a time-limited exception for newly practicing EPs or new hospitals who would not otherwise be able to avoid payment adjustments, and unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis. We also solicit comment on a fourth category of exception due to a combination of clinical features limiting a provider's interaction with patients and lack of control over the availability of Certified EHR technology at their practice locations.

d. Modifications to Medicaid EHR Incentive Program

We propose to expand the definition of what constitutes a Medicaid patient encounter, which is a required eligibility threshold for the Medicaid EHR Incentive Programs. We propose to include encounters for individuals enrolled in a Medicaid program, including Title XXI-funded Medicaid expansion encounters (but not separate CHIP programs. We also propose flexibility in the look-back period for patient volume to be over the 12 months preceding attestation, not tied to the prior calendar year.

We also propose to make eligible approximately 12 additional children's hospitals that have not been able to participate to date, despite meeting all other eligibility criteria, because they do not have a CMS Certification Number since they do not bill Medicare.

e. Stage 2 Timeline Delay

Finally, we propose a minor delay of the implementation of the onset of Stage 2 criteria. In the Stage 1 final rule, we established that any provider who first attested to Stage 1 criteria for Medicare in 2011 would begin using Stage 2 criteria in 2013. This proposed rule delays the onset of those Stage 2 criteria until 2014, which we believe provides the needed time for vendors to develop Certified EHR Technology.

3. Summary of Costs and Benefits

This proposed rule is anticipated to have an annual effect on the economy of $100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rule. The total Federal cost of the Medicare and Medicaid EHR Incentive Programs is estimated to be $14.6 billion in transfers between 2014 and 2019. In this proposed rule we have not quantified the overall benefits to the industry, nor to eligible hospitals, or EPs in the Medicare and Medicaid EHR Incentive Programs. Information on the costs and benefits of adopting systems specifically meeting the requirements for the EHR Incentive Programs has not yet been collected and information on costs and benefits overall is limited. Nonetheless, we believe there are substantial benefits that can be obtained by eligible hospitals and EPs, including reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, increased patient safety, and reduced medical errors. There is evidence to support the cost-saving benefits anticipated from wider adoption of EHRs.

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2014	$1.3	$1.2	$0.4	$0.8	$3.7
2015	1.2	1.1	0.5	0.9	3.7
2016	0.6	0.8	0.9	1.0	3.3
2017	0.0	0.2	1.0	1.0	2.2
2018	−0.2	−0.2	0.6	0.9	1.1
2019	−0.0	−0.2	0.1	0.7	0.6

Amounts are in 2012 billions.

B. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage (MA) Organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology. On July 28, 2010 we published in the **Federal Register** (75 FR 44313 through 44588) a final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program,'' that specified the Stage 1 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, calculation of the incentive payment amounts, and other program participation requirements (hereinafter referred to as the Stage 1 final rule). (For a full explanation of the amendments made by ARRA, see the final rule (75 FR 44316).) In that final rule, we also detailed that the Medicare and Medicaid EHR Incentive Programs would consist of 3 different stages of meaningful use requirements.

For Stage 1, CMS and the Office of the National Coordinator for Health Information Technology (ONC) worked closely to ensure that the definition of meaningful use of Certified EHR Technology and the standards and certification criteria for Certified EHR Technology were coordinated. Current ONC regulations may be found at 45 CFR part 170. For Stage 2, CMS and ONC will again work together to align our regulations.

We urge those interested in this proposed rule to also review the ONC proposed rule on standards and implementation specifications for Certified EHR Technology. Readers may also visit *http://healthit.hhs.gov* and *http://www.cms.hhs.gov/EHRincentiveprograms* for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

II. Provisions of the Proposed Regulations

A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs

1. Uniform Definitions

In the Stage 1 final rule, we finalized many uniform definitions for the Medicare FFS, MA, and Medicaid EHR incentive programs. These definitions are set forth in part 495 subpart A of the regulations, and we are proposing to maintain most of these definitions, including, for example, ''Certified EHR Technology,'' ''Qualified EHR,'' ''Payment Year,'' and ''First, Second, Third, Fourth, Fifth, and Sixth Payment Year.'' We note that our definitions of ''Certified EHR Technology'' and ''Qualified EHR'' incorporate the definitions adopted by ONC, and to the extent that ONC's definitions are revised, our definitions would also incorporate those changes. For these definitions, we refer readers to ONC's standards and certification criteria proposed rule that is published elsewhere in this issue of the **Federal Register**. We are revising the descriptions of the EHR reporting period to clarify that for providers who are demonstrating meaningful for the first time their EHR reporting period is 90 days regardless of payment year. We propose to add definitions for the applicable EHR reporting period that would be used in determining the payment adjustments, as well as a definition of a payment adjustment year, as discussed in section II.D. of this proposed rule.

2. Meaningful EHR User

We propose to include clinical quality measure reporting as part of the definition of ''meaningful EHR user'' instead of as a separate meaningful use objective under 42 CFR 495.6. This change is explained in section II.A.3.d. in the context of the proposed Stage 2 criteria for meaningful use.

The third paragraph of the definition of meaningful EHR user at 42 CFR 495.4 currently read as follows: ''(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during the EHR reporting period during the payment year must occur at a practice/location or practices/locations equipped with certified EHR technology.'' We propose to revise the third paragraph of the definition of meaningful EHR user at 42 CFR 495.4 to read as follows: ''(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or during an applicable EHR reporting period for a payment adjustment year) must occur at a practice/location or practices/locations equipped with Certified EHR Technology.'' This change is to include the payment adjustment in this definition. Currently, it only refers to the incentives.

3. Definition of Meaningful Use

a. Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade or meaningfully use Certified EHR Technology if they are to receive incentives under Title XIX. Certified EHR Technology used in a meaningful way is one piece of the broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

As we explained in our Stage 1 meaningful use rule, we seek to balance the sometimes competing considerations of health system advancement (for example, improving health care quality, encouraging widespread EHR adoption, promoting innovation) and minimizing burdens on health care providers given the short timeframe available under the HITECH Act.

Based on public and stakeholder input received during our Stage 1 rulemaking, we laid out a phased approach to meaningful use. Such a phased approach encompasses reasonable criteria for meaningful use based on currently available technology capabilities and provider practice experience, and builds up to a more robust definition of meaningful use as technology and capabilities evolve. The HITECH Act acknowledges the need for this balance by granting the Secretary the discretion to require more stringent measures of meaningful use over time. Ultimately, consistent with other provisions of law, meaningful use of Certified EHR Technology should result in health care that is patient-centered, evidence-based, prevention-oriented, efficient, and equitable.

Under this phased approach to meaningful use, we update the criteria of meaningful use through staggered rulemaking. We published the Stage 1 final rule July 28, 2010, and this rule outlines our proposed Stage 2 approach. We currently anticipate at least one additional update, and anticipate updating the Stage 3 criteria with another proposed rule by early 2014. The stages represent an initial graduated approach to arriving at the ultimate goal.

- Stage 1: The Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focused on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information. Stage 1 focused heavily on establishing the functionalities in Certified EHR Technology that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in certified EHR technology at the onset of the program and requiring that the EP, eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we created a strong foundation to build on in later years. Though some functionalities were optional in Stage 1, all of the functionalities are considered crucial to maximize the value to the health care system provided by Certified EHR Technology. We encouraged all EPs, eligible hospitals and CAHs to be proactive in implementing all of the functionalities of Stage 1 in order to prepare for later stages of meaningful use, particularly functionalities that improve patient care, the efficiency of the health care system and public and population health. The specific criteria for Stage 1 of meaningful use are discussed in the Stage 1 final rule, (published on July 28, 2010 (75 FR 44314 through 44588). We are proposing certain changes to the Stage 1 criteria in section II.B.3.b. of this proposed rule.
- Stage 2: Our Stage 2 goals, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria with a focus on ensuring that the meaningful use of EHRs supports the aims and priorities of the National Quality Strategy. Specifically, Stage 2 meaningful use criteria encourage the use of health IT for continuous quality improvement at

the point of care and the exchange of information in the most structured format possible. Stage 2 meaningful use requirements include rigorous expectations for health information exchange including: more demanding requirements for e-prescribing; incorporating structured laboratory results; and the expectation that providers will electronically transmit patient care summaries to support transitions in care across unaffiliated providers, settings and EHR systems. Increasingly robust expectations for health information exchange in Stage 2 and Stage 3 will support the goal that information follows the patient. In addition, as we forecasted in the Stage 1 final rule, we now consider nearly every objective that was optional for Stage 1 to be required in Stage 2, and we reevaluated the thresholds and exclusions of all the measures.

- Stage 3: We anticipate that Stage 3 meaningful use criteria will focus on: promoting improvements in quality, safety and efficiency leading to improved health outcomes; focusing on decision support for national high priority conditions; patient access to self-management tools; access to comprehensive patient data through robust, patient-centered health information exchange; and improving population health. For Stage 3, we currently intend to propose higher standards for meeting meaningful use. For example, we intend to propose that every objective in the menu set for Stage 2 (as described later in this section) be included in Stage 3 as part of the core set. While the use of a menu set allows providers flexibility in setting priorities for EHR implementation and takes into account their unique circumstances, we maintain that all of the objectives are crucial to building a strong foundation for health IT and to meeting the objectives of the Act. In addition, as the capabilities of HIT infrastructure increase, we may raise the thresholds for these objectives in both Stage 2 and Stage 3.

In the Stage 1 final rule (75 FR 44323), we published the following table with our expected timeline for the stages of meaningful use.

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR AS FINALIZED IN 2010

First payment year	Payment year				
	2011	2012	2013	2014	2015
2011	Stage 1	Stage 1	Stage 2	Stage 2	TBD.
2012		Stage 1	Stage 1	Stage 2	TBD.
2013			Stage 1	Stage 1	TBD.
2014				Stage 1	TBD.

We are proposing changes to this timeline as well as its extension beyond 2014. Under the timeline used in the Stage 1 final rule (75 FR 44323), an EP, eligible hospital, or CAH that became a meaningful EHR user for the first time in 2011 would need to begin their EHR reporting period for Stage 2 on January 1, 2013 or October 1, 2012, respectively. We anticipate publishing a final rule by summer 2012. The HIT Policy Committee recommended we delay by 1 year the start of Stage 2 for providers who became meaningful EHR users in 2011. Stage 2 of meaningful use requires changes to both technology and workflow that cannot reasonably be expected to be completed in the time between the publication of the final rule and the start of the EHR reporting periods. We have heard similar concerns from other stakeholders and agree that, based on our proposed definition of meaningful use for Stage 2, providers could have difficulty implementing these changes in time. Therefore, we are proposing a 1-year extension of Stage 1 of meaningful use for providers who successfully demonstrated meaningful use for 2011. Our proposed timeline through 2021 is displayed in Table 2. We refer readers to II.D.2 of this proposed rule for a discussion of the applicable EHR reporting period that would be used to determine whether providers are subject to payment adjustments.

TABLE 2—STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	2	2	3	3	TBD	TBD	TBD	TBD.
2012		1	1	2	2	3	3	TBD	TBD	TBD	TBD.
2013			1	1	2	2	3	3	TBD	TBD	TBD.
2014				1	1	2	2	3	3	TBD	TBD.
2015					1	1	2	2	3	3	TBD.
2016						1	1	2	2	3	3.
2017							1	1	2	2	3.

Please note that the Medicare EHR incentive program and the Medicaid EHR incentive program have different rules regarding the number of payment years available, the last year for which incentives may be received, and the last payment year for initiating the program. Medicaid EPs and eligible hospitals can receive a Medicaid EHR incentive payment for ''adopting, implementing, and upgrading'' (AIU) to Certified EHR Technology for their first payment year, which is not reflected in Table 2. For example, a Medicaid EP who earns an incentive payment for AIU in 2013 would have to meet Stage 1 of meaningful use in his or her next 2 payment years (2014 and 2015). The applicable payment years and the incentive payments available for each program are discussed in the Stage 1 final rule.

If there will be a Stage 4 of meaningful use, we expect to update this table in the rulemaking for Stage 3.

b. Changes to Stage 1 Criteria for Meaningful Use

We propose the following changes to the objectives and associated measures for Stage 1. As explained later in this proposed rule, most of these changes would be optional for Stage 1 in 2013 and would be required for Stage 1 beginning in 2014 (CY for EPs, FY for eligible hospitals/CAHs). We do not believe that this creates an additional hardship as providers would have the option of completing Stage 1 in the same manner in 2013 as in 2011 and 2012, and in fact, the changes we propose create flexibility for EPs, eligible hospitals, and CAHs seeking to achieve Stage 1 meaningful use objectives.

The current denominator for the CPOE objective measure for Stage 1 is the number of unique patients with at least one medication in their medication list seen by an EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period. We created this denominator in response to comments that our original Stage 1 proposed denominator for this measure, the number of orders for medications, is difficult to measure. Following publication of the final rule, we have received nearly unanimous feedback from providers that the logical denominator for this measure is the number of orders for medications and that it is measurable. For more details please reference the discussion of the Stage 2 CPOE objective. Beginning in 2013 (CY for EPs, FY for eligible hospitals/CAHs), we propose to allow providers in Stage 1 to use the alternative denominator of the number of medication orders created by the EP or in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period (for further explanation of this alternative denominator, see the discussion of the proposed CPOE objective in the Stage 2 criteria section). A provider seeking to meet Stage 1 in 2013 could use either the current or the proposed alternative denominator to calculate the percentage for the CPOE measure.

Starting with the EHR reporting periods in FY/CY 2014, the proposed ''alternative denominator'' would be required for all providers in Stage 1 and Stage 2.

For the objective of record and chart changes in vital signs, our Stage 2 proposal would allow an EP to split the exclusion and exclude blood pressure only or height/weight only (for more detail, see the discussion of this objective in the Stage 2 criteria section). We propose an identical change to the Stage 1 exclusion as well, starting in CY 2013. We also propose changing the age limitations on vital signs for Stage 2 (for more detail, see the discussion of this objective in the Stage 2 criteria section). We propose identical changes to the age limitations on vital signs for Stage 1, starting in 2013 (CY for EPs, FY for eligible hospitals/CAHs). These changes to the exclusion and age limitations would be an alternative in 2013 to the current Stage 1 requirements and would be required for Stage 1 beginning in 2014. We have found the objective of ''capability to exchange key clinical information'' to be surprisingly difficult for providers to understand, which has made the objective considerably more difficult to achieve than we envisioned in the Stage 1 final rule. As the measure for this objective is simply a test with no associated requirement for follow-up submission, we are concerned the value of this objective is not sufficient to justify the burden of compliance. However, we also strongly believe that meaningful use of EHRs must ultimately involve real and ongoing electronic health information exchange to support care coordination, as the Stage 2 objectives on this subject (described below) make clear. We considered four options for this objective, and welcome comment on all four, that variously reduce or eliminate the burden of the objective or increase the value of the objective. The first option we considered is removal of this objective. This acknowledges our experience with Stage 1 and the limited benefit of just a test. The second option is to require that the test be successful. This would increase the value of the objective and eliminate a common question we receive on what happens if the test is unsuccessful. The third option is to eliminate the objective, but require that providers select either the Stage 1 medication reconciliation objective or the Stage 1 summary of care at transitions of care and referrals from the menu set. This would eliminate the burden and complexity of the test, but preserve the domain of care coordination for Stage 1. The fourth option is to move from a test to one case of actual electronic transmission of a summary of care document for a real patient either to another provider of care at a transition or referral or to a patient authorized entity. This would increase the benefit of the objective and reduce the complexity of the defining the parameters of the test, but potentially increases the real burden of compliance significantly beyond what is currently included in Stage 1. We are proposing the first option to remove this objective and measure from the Stage 1 core set beginning in 2013 (CY for EPs, FY for eligible hospitals/CAHs). In Stage 2, we propose to move to actual use cases of electronic exchange of health information as discussed later in this proposed rule, which would require significant testing in the years of Stage 1. We encourage comments on all four options and will evaluate them again in light of the public comment received.

We propose for Stage 2 a new method for making patient information available electronically, which would enable patients to view online and download their health information and hospital admission information. We discuss in the Stage 2 criteria section the proposed ''view, download, and transmit'' objectives for EPs and hospitals. Starting in 2014, Certified EHR Technology will no longer be certified to the Stage 1 EP and hospital core objectives of providing patients with electronic copies of their health information and discharge instructions upon request, nor will it support the Stage 1 EP menu objective of providing patients with timely electronic access to their health information. Therefore starting in 2014, for Stage 1, we propose to replace these objectives with the new ''view online, download and transmit'' objectives. We discuss these objectives further in our proposed Stage 2 criteria.

We are proposing a revised definition of a meaningful EHR user which would incorporate the requirement to submit clinical quality measures, as discussed in section II.A.2. of this proposed rule, and as such are removing the objective to submit clinical quality measures beginning in 2013 and the associated regulation text under 45 CFR 495.6 for Stage 1 to conform with this change in the definition of a meaningful EHR user.

For the Stage 1 public health objectives, beginning in 2013, we also propose to add ''except where prohibited'' to the regulation text, because we want to encourage all EPs, eligible hospitals, and CAHs to submit electronic immunization data, even when not required by State/local law. Therefore, if they are authorized to submit the data, they should do so even if it is not required by either law or practice. There are a few instances where some EPs, eligible hospitals, and CAHs are prohibited from submitting to a State/local immunization registry. For example, in sovereign tribal areas that do not permit transmission to an immunization registry or when the immunization registry only accepts data from certain age groups (for example, adults).

TABLE 3—CHANGES TO STAGE 1

Stage 1 objective	Proposed changes	Effective year (CY/FY)
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines.	Change: Addition of an alternative measure ..... More than 30 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	2013–Only (Optional).
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines.	Change: Replacing the measure ..... More than 30 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	2014–Onward (Required).
Record and chart changes in vital signs	Change: Addition of alternative age limitations ..... More than 50 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height and weight (for all ages) recorded as structured data.	2013–Only (Optional).
Record and chart changes in vital signs	Change: Addition of alternative exclusions ..... Any EP who (*1*) Sees no patients 3 years or older is excluded from recording blood pressure; (*2*) Believes that all three vital signs of height, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them; (*3*) Believes that height and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or (*4*) Believes that blood pressure is relevant to their scope of practice, but height and weight are not, is excluded from recording height and weight.	2013–Only (Optional).
Record and chart changes in vital signs	Change: Age Limitations on Growth Charts and Blood Pressure ..... More than 50 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height and weight (for all ages) recorded as structured data.	2014–Onward (Required)
Record and chart changes in vital signs	Change: Changing the age and splitting the EP exclusion ..... Any EP who (*1*) Sees no patients 3 years or older is excluded from recording blood pressure; (*2*) Believes that all three vital signs of height, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them; (*3*) Believes that height and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or (*4*) Believes that blood pressure is relevant to their scope of practice, but height and weight are not, is excluded from recording height and weight.	2014–Onward (Required).
Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.	Change: Objective is no longer required	2013–Onward (Required).
Report ambulatory (hospital) clinical quality measures to CMS or the States.	Change: Objective is incorporated directly into the definition of a meaningful EHR user and eliminated as an objective under 42 CFR 495.6.	2013–Onward (Required)
EP Objective: Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.	Change: Replace these three objectives with the Stage 2 objective and one of the two Stage 2 measures. EP Objective: Provide patients the ability to view online, download and transmit their health information within 4 business days of the information being available to the EP.	2014–Onward (Required).
Hospital Objective: Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	EP Measure: More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.	
EP Objective: Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within 4 business days of the information being available to the EP.	Hospital Objective: Provide patients the ability to view online, download and transmit information about a hospital admission. Hospital Measure: More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.	
Public Health Objectives:	Change: Addition of ''except where prohibited'' to the objective regulation text for the public health objectives under 42 CFR 495.6.	2013–Onward (Required).

c. State Flexibility for Stage 2 of Meaningful Use

We propose to offer States flexibility with the public health measures in Stage 2, similar to that of Stage 1, subject to the same conditions and standards as the Stage 1 flexibility policy. This applies to the public health measures as well as the measure to generate lists of specific conditions to use for quality improvement, reduction of disparities, research or outreach.

In addition, whether moved to the core or left in the menu, States may also specify the means of transmission of the data or otherwise change the public health measure, as long as it does not require EHR functionality above and beyond that which is included in the ONC EHR certification criteria as finalized for Stage 2 of meaningful use.

We solicit comment on extending State flexibility as described for Stage 2 of meaningful use and whether this remains a useful tool for State Medicaid agencies.

d. Stage 2 Criteria for Meaningful Use (Core Set and Menu Set)

We are proposing to continue the Stage 1 concept of a core set of objectives and a menu set of objectives for Stage 2. In the Stage 1 final rule (75 FR 44322), we indicated that for Stage 2, we expected to include the Stage 1 menu set objectives in the core set. We propose to follow that approach for our Stage 2 core set with two exceptions. We are proposing to keep the objective of ''capability to submit electronic syndromic surveillance data to public health agencies'' in the menu set for EPs. Our experience with Stage 1 is that very few public health agencies have the ability to accept ambulatory syndromic surveillance data electronically and those that do are less likely to support EPs than hospitals; therefore we do not believe that current infrastructure supports moving this objective to the core set for EPs. We are also proposing to keep the objective of ''record advance directives'' in the menu set for eligible hospitals and CAHs. As we stated in our Stage 1 final rule (75 FR 44345), we have continuing concerns that there are potential conflicts between storing advance directives and existing State laws.

We are proposing new objectives for Stage 2, some of which would be part of the Stage 2 core set and others would make up the Stage 2 menu set, as discussed below with each objective. We are proposing to eliminate certain Stage 1 objectives for Stage 2, such as the objective for testing the capability to exchange key clinical information. We are also proposing to combine some of the Stage 1 objectives for Stage 2. For example, the objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list would not be separate objectives for Stage 2. Instead, we would combine these objectives with the objective of providing a summary of care record for each transition of care or referral by including them as required fields in the summary of care.

We are proposing a total of 17 core objectives and 5 menu objectives for EPs. We propose that an EP must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 5 menu objectives. This is a change from our current Stage 1 policy where an EP could reduce by the number of exclusions applicable to the EP the number of menu set objectives that the EP would otherwise need to meet. We received feedback on Stage 1 that we have received from providers and health care associations leads us to believe that most EPs had difficulty understanding the concept of deferral of a menu objective in Stage 1, so we are proposing this change for Stage 2, as well as for Stage 1 beginning in 2014, to make the selection of menu objectives easier for EPs. We are proposing this change because we are concerned that under the current Stage 1 requirements EPs could select and exclude menu objectives when there are other menu objectives they can legitimately meet, thereby making it easier for them to demonstrate meaningful use than EPs who attempt to legitimately meet the full complement of menu objectives. Although we provided greater flexibility to do this in the selection of Stage 1 menu objectives through 2013, we believe that EPs participating in Stage 1 and Stage 2 starting in 2014 should focus solely on those objectives they can meet rather than those for which they have an exclusion. In addition, we have provided exclusions for the Stage 2 menu objectives that we believe will accommodate EPs who are unable to meet certain objectives because of scope of practice.

However, just as we signaled in our Stage 1 regulation, we currently intend to propose in our next rulemaking that every objective in the menu set for Stage 2 (as described later in this section) be included in Stage 3 as part of the core set. In the case where an EP meets the criteria for the exclusions for 3 or more of the Stage 2 menu objectives, the EP would have more exclusions than the allowed deferrals. EPs in this situation would attest to an exclusion for 1 or more menu objectives in his or her attestation to meaningful use. In doing so, the EP would be attesting that he or she also meets the exclusion criteria for all of the menu objectives that he or she did not choose. The same policy would also apply for the Stage 1 menu objectives for EPs beginning in 2014.

We propose a total of 16 core objectives and 4 menu objectives for eligible hospitals and CAHs for Stage 2. We propose that an eligible hospital or CAH must meet the criteria or an exclusion for all of the core objectives and the criteria for 2 of the 4 menu objectives. The policy for exclusions for EPs discussed in the preceding paragraph would also apply to eligible hospitals and CAHs for Stage 1 beginning in 2014 and for Stage 2.

(1) Discussion of Whether Certain EPs, Eligible Hospitals or CAHs Can Meet All Stage 2 Meaningful Use Objectives Given Established Scopes of Practice

We do not believe that any of the proposed new objectives for Stage 2 make it impossible for any EP, eligible hospital or CAH to meet meaningful use. Where scope of practice may prevent an EP, eligible hospital or CAH from meeting the measure associated with an objective we discuss the barriers and include exclusions in our descriptions of the individual objectives later. We are proposing to include new exclusion criteria when necessary for new objectives, continue the Stage 1 exclusions for Stage 2, and continue the option for EPs and hospitals to defer some of the objectives in the menu set unless they meet the exclusion criteria for more objectives than they can defer as explained previously.

We recognize that at the time of publication, our data (derived internally from attestations) only reflects the meaningful use attestation from Medicare providers. Before the publication of the final rule, we plan on adjusting the data on the successful attestations to date to reflect the experience of successful Medicaid meaningful EHR users. This may result in changes to our current assumptions based upon the data available at the time of the proposed rule, especially given the different eligible professional types in the Medicaid EHR Incentive Program. It may be that different eligible professional types may have different levels of success in meeting the meaningful use measure thresholds, given their scope of practice.

(2) EPs Practicing in Multiple Practices/Locations

We propose for Stage 2 to continue our policy that to be a meaningful EHR user, an EP must have 50 percent or more of his or her outpatient encounters

during the EHR reporting period at a practice/location or practices/locations equipped with Certified EHR Technology. An EP who does not conduct at least 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations equipped with Certified EHR Technology. For example, if the EP practices at a federally qualified health center (FQHC) and within his or her individual practice at 2 different locations, we would include in our review all 3 of these locations, and Certified EHR Technology would have to be available at one location or a combination of locations where the EP has 50 percent or more of his or her patient encounters. If Certified EHR Technology is only available at one location, then only encounters at this location would be included in meaningful use assuming this one location represents 50 percent or more of the EP's patient encounters. If Certified EHR Technology is available at multiple locations that collectively represent 50 percent or more of the EP's patient encounters, then all encounters from those locations would be included in meaningful use.

We have received many inquiries on this requirement since the publication of the Stage 1 final rule. We define patient encounter as any encounter where a medical treatment is provided and/or evaluation and management services are provided. This includes both individually billed events and events that are globally billed, but are separate encounters under our definition. We have also received requests for clarification on what it means for a practice/location to be equipped with Certified EHR Technology. We define a practice/location as equipped with Certified EHR Technology if the record of the patient encounter that occurs at that practice/location is created and maintained in Certified EHR Technology. This can be accomplished in three ways: Certified EHR Technology could be permanently installed at the practice/location, the EP could bring Certified EHR Technology to the practice/location on a portable computing device, or the EP could access Certified EHR Technology remotely using computing devices at the practice/location. Although it is currently allowed under Stage 1 for an EP to create a record of the encounter without using Certified EHR Technology at the practice/location and then later input that information into Certified EHR Technology that exists at a different practice/location, we do not believe this process takes advantage of the value Certified EHR Technology offers. We are proposing not to allow this practice beginning in 2013. We have also received inquiries whether the practice locations have to be in the same State, to which we clarify that they do not. Finally, we received inquiries regarding the interaction with hospital-based EP determination. There is no interaction. The determination of whether an EP is hospital-based or not occurs prior to the application of this policy, so only non-hospital based eligible professionals are included. Furthermore, this policy, like all meaningful use policies for EPs, only applies to outpatient settings (all settings except the inpatient and emergency department of a hospital).

(3) Discussion of the Reporting Requirements of the Measures Associated With the Stage 2 Meaningful Use Objectives

In our experience with Stage 1, we found the distinction between limiting the denominators of certain measures to only those patients whose records are maintained using Certified EHR Technology, but including all patients in the denominators of other measures, to be complicated for providers to implement. We are proposing to remove this distinction for Stage 2 and instead include all patients in the denominators of all of the measures associated with the meaningful use objectives for Stage 2. We believe that by the time an EP, eligible hospital, or CAH has reached Stage 2 of meaningful use all or nearly all of their patient population should be included in their Certified EHR Technology, making this distinction no longer relevant.

We also continue our policy that EPs practicing in multiple locations do not have to include patients seen at practices/locations that are not equipped with Certified EHR Technology in the calculations of the meaningful use measures as long as the EP has 50 percent of their patient encounters during the EHR reporting period at locations equipped with Certified EHR Technology.

We are proposing new objectives that could increase reporting burden. To minimize the burden, we are proposing to create a uniform set of denominators that would be used for all of the Stage 2 meaningful use objectives, as discussed later.

Many of our meaningful use objectives use percentage-based measures wherever possible and if appropriate. To provide a check on the burden of reporting of meaningful use, we propose for Stage 2 to use 1 of 4 denominators for each of the measures associated with the meaningful use objectives. We focus on denominators because the action that moves something from the denominator to the numerator usually requires the use of Certified EHR Technology by the provider. These actions are easily tracked by the technology.

The four proposed denominators for EPs:

- Unique patients seen by the EP during the EHR reporting period (stratified by age or previous office visit).
- Number of orders (medication, labs, radiology).
- Office visits, and
- Transitions of care/referrals.

The term ''unique patient'' means that if a patient is seen or admitted more than once during the EHR reporting period, the patient only counts once in the denominator. Patients seen or admitted only once during the EHR reporting period would count once in the denominator. A patient is seen by the EP when the EP has an actual physical encounter with the patient in which they render any service to the patient. A patient seen through telemedicine would also still count as a patient ''seen by the EP.'' In cases where the EP and the patient do not have an actual physical or telemedicine encounter, but the EP renders a minimal consultative service for the patient (like reading an EKG), the EP may choose whether to include the patient in the denominator as ''seen by the EP'' provided the choice is consistent for the entire EHR reporting period and for all relevant meaningful use measures. For example, a cardiologist may choose to exclude patients for whom they provide a one-time reading of an EKG sent to them from another provider, but include more involved consultative services as long as the policy is consistent for the entire EHR reporting period and for all meaningful use measures that include patients ''seen by the EP.'' EPs who never have a physical or telemedicine interaction with patients must adopt a policy that classifies at least some of the services they render for patients as ''seen by the EP,'' and this policy must be consistent for the entire EHR reporting period and across meaningful use measures that involve patients ''seen by the EP''—otherwise, these EPs would not be able to satisfy meaningful use, as they would have denominators of zero for some measures. In cases where the patient is seen by a member of the EP's clinical staff the EP can include or not include those patients in their denominator at their discretion as

long as the decision applies universally to all patients for the entire EHR reporting period and the EP is consistent across meaningful use measures. In cases where a member of the EP's clinical staff is eligible for the Medicaid EHR incentive in their own right (for example, nurse practitioners (NPs) and certain physician assistants (PA)), patients seen by NPs or PAs under the EP's supervision can be counted by both the NP or PA and the supervising EP as long as the policy is consistent for the entire EHR reporting period.

An office visit is defined as any billable visit that includes: (1) Concurrent care or transfer of care visits; (2) consultant visits; or (3) prolonged physician service without direct, face-to-face patient contact (for example, telehealth). A consultant visit occurs when a provider is asked to render an expert opinion/service for a specific condition or problem by a referring provider. The visit does not have to be individually billable in instances where multiple visits occur under one global fee. Transitions of care are the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. Currently, the meaningful use measures that use transitions of care require there to be a receiving provider of care to accept the information. Therefore, a transition home without any expectation of follow-up care related to the care given in the prior setting by another provider is not a transition of care for purpose of Stage 2 meaningful use measures as there is no provider recipient. A transition within one setting of care does not qualify as a transition of care. Referrals are cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well. (Please note that a ''referral'' as defined here and elsewhere in this proposed rule is only intended to apply to the EHR Incentive Programs and is not applicable to other Federal regulations.)

The four proposed denominators for eligible hospitals and CAHs:

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period (stratified by age).
- Number of orders (medication, labs, radiology).
- Inpatient bed days.
- Transitions of care.

The explanation of ''unique patients'' and ''transitions of care'' in the preceding paragraph for EPs also applies for eligible hospitals and CAHs. Admissions to the eligible hospital or CAH can be calculated using one of two methods currently available under Stage 1 of meaningful use. The observation services method includes all patients admitted to the inpatient department (POS 21) either directly or through the emergency department and patients who initially present to the emergency department (POS 23) and receive observation services. Details on observation services can be found in the Medicare Benefit Policy Manual, Chapter 6, Section 20.6. Patients who receive observation services under both the outpatient department (POS 22) and emergency department (POS 23) should be included in the denominator under this method. The all emergency department method includes all patients admitted to the inpatient department (POS 21) either directly or through the emergency department and all patients receiving services in the emergency department (POS 23).

Inpatient bed days are the admission day and each of the following full 24-hour periods during which the patient is in the inpatient department (POS 21) of the hospital. For example, a patient admitted to the inpatient department at noon on June 5th and discharged at 2 p.m. on June 7th would be admitted for 2-patient days: the admission day (June 5th) and the 24 hour period from 12 a.m. on June 6th to 11:59 p.m. on June 6th.

(4) Discussion of the Relationship of Meaningful Use to Certified EHR Technology

We propose to continue our policy of linking each meaningful use objective to certification criteria for Certified EHR Technology. As with Stage 1, EPs, eligible hospitals, and CAHs must use the capabilities and standards that are certified to meet the objectives and associated measures for Stage 2 of meaningful use. In meeting any objective of meaningful use, an EP, eligible hospital or CAH must use the capabilities and standards that are included in certification. In some instances, meaningful use objectives and measures require use that is not directly enabled by certified capabilities and/or standards. In these cases, the EP, eligible hospital and CAH is responsible for meeting the objectives and measures of meaningful use, but the way they do so is not constrained by the capabilities and standards of Certified EHR Technology. For example, in e-Rx and public health reporting, Certified EHR Technology applies standards to the message being sent and enables certain capabilities for transmission in 2014; however, to actually engage in e-Rx or public health reporting many steps must be taken despite these standards and capabilities such as contacting both parties and troubleshooting issues that may arise through the normal course of business.

(5) Discussion of the Relationship Between a Stage 2 Meaningful Use Objective and its Associated Measure

We propose to continue our Stage 1 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective, meeting the criteria of the measure means that the provider has met the objective for Stage 2.

(6) Objectives and Their Associated Measures

(a) Objectives and Measures Carried Over (Modified or Unmodified) From Stage 1 Core Set to Stage 2 Core Set

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.

We propose to continue to define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process.

CPOE improves quality and safety by allowing clinical decision support at the point of the order and therefore influences the initial order decision. CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the possibility of communication and other errors. Consistent with the recommendations of the HIT Policy Committee, we would expand the orders included in the objective to medication (which was included in Stage 1), laboratory, and radiology. We believe that the expansion to laboratory and radiology furthers the goals of the CPOE objective, that such orders are commonly included in CPOE roll outs and that this is a logical step in the progression of meaningful use.

Our experience with Stage 1 of meaningful use demonstrated that our definition of CPOE in the Stage 1 final

rule does not indicate when in the ordering process the CPOE function must be utilized. We provided guidance at: *https://questions.cms.hhs.gov/app/answers/detail/a_id/10134/* on the Stage 1 criteria to say that the CPOE function should be used the first time the order becomes part of the patient's medical record and before any action can be taken on the order. Our experience shows that the limiting criterion is the first time the order becomes part of the patient's medical record rather than the limitation to licensed healthcare professionals entering the order. Our experience has also demonstrated that each provider must make the decision of whether the record of an order is part of the patient's medical record independently as the possible variations in process and record keeping are too numerous for a universal statement on when in the process an order becomes part of the patient's medical record. To further CPOE's ability to improve safety and efficiency and to provide greater clarity for Stage 2 of meaningful use, we are proposing to redefine the point in the ordering process when CPOE must be utilized. We propose that to be considered CPOE, the CPOE function must be utilized to create the first record of any type for the order. This removes the possibility that a record of the order could be created prior to CPOE, but not be part of the patient's medical record. In a practice, this means the originating provider (the provider whose judgment creates the order) must personally use the CPOE function, verbally communicate the order to someone else who will use the CPOE function, or give an electronic or written order that must not be retained in any way once the CPOE function has been utilized. This is a meaningful use requirement and does not affect any other legal or regulatory requirements as to what constitutes a patient's health record or order. With this new proposal, we invite public comment on whether the stipulation that the CPOE function be used only by licensed healthcare professionals remains necessary or if CPOE can be expanded to include nonlicensed healthcare professionals such as scribes.

Proposed Measure: More than 60 percent of medication, laboratory, and radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.

In Stage 1 of meaningful use, we adopted a measure of more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE. In the Stage 1 final rule, we adopted a threshold of 60 percent for this measure for Stage 2.

Our experience with Stage 1 of meaningful use has shown that a denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers. Many providers have voluntarily provided information on the number of medication orders in their clinic or hospital. However, this does not guarantee such a denominator would be feasible for all providers. We believe the EHRs can calculate a denominator of all orders entered into the Certified EHR Technology, with the numerator limited to those entered into Certified EHR Technology using CPOE. Potentially, this would exclude those orders that are never entered into the Certified EHR Technology in any manner. The provider would be responsible for including those orders in their denominator. However, we believe that providers using Certified EHR Technology use it as the patient's medical record; therefore, an order not entered into Certified EHR Technology would be an order that is not entered into a patient's medical record. For this reason, we expect that orders given for patients that are never entered into the Certified EHR Technology to be few in number or non-existent. We encourage comments on whether a denominator other than number of medication, laboratory, and radiology orders created by the EP or in the hospital would be needed for EPs and/or hospitals. For example, the HIT Policy Committee recommended a denominator of ''patients with at least one type of order.'' We are proposing, however, a different denominator for this measure, which we believe would be possible to collect given our experience in Stage 1 of meaningful use and a much more accurate measure of actual CPOE usage. The denominator of ''patients with at least one type of order'' is a proxy measure for the number of orders issued by the EP, eligible hospital or CAH. The accuracy of that proxy is dependent on the frequency in which an encounter results in an order. For example, an EP whose scope of practice is such that they order a medication on nearly every encounter would have every encounter as an opportunity to move the patient from the denominator to a numerator. The 2005 National Ambulatory Medical Care Survey (referenced in the Stage 1 final rule, 75 FR 44333) found that 66 percent of office-based visits had any type of medication order. EPs whose office visits are consistent with the survey findings would have a third fewer opportunities to move the patient from the denominator to the numerator. We believe a direct measure of the number of orders is feasible and more accurate as it is not dependent on the frequency of orders. We encourage comments on whether the barriers to collecting information for our proposed denominator would be greater in a hospital or ambulatory setting. As we noted previously, the denominator used in Stage 1 (as well as the denominator recommended by the HIT Policy Committee) is much more representative of CPOE use in a hospital setting than an ambulatory setting, so these settings could require different denominators or measures. We request comment on different denominators or measures and encourage any commenter proposing an alternative denominator to discuss whether the proposed threshold or an alternative threshold should be used for this measure and to include any exclusions they believe are necessary based on their alternative denominator.

Based on our experience with attestation data from Stage 1, we continue to believe that the 60 percent threshold that we finalized previously for Stage 2 is appropriate. We also believe that this threshold translates to our new measure. The HIT Policy Committee recommended including laboratory and radiology orders in the measure, but as ''yes/no'' attestations of one order being entered using CPOE rather than at the 60 percent threshold. We believe this is unnecessary given the advance of CPOE. In our discussions with EPs, eligible hospitals and CAHs we find that they do not roll out CPOE with only one order type, but rather include medications, laboratory and radiology/imaging orders as a package. We are also concerned about the possibility that an EP, eligible hospital or CAH could create a test environment to issue the one order and not roll out the capability widely or at all. We welcome comment on whether laboratory and radiology orders are sufficiently different in the use of CPOE that they would require a different threshold and whether such a threshold should be a lower percentage or a yes/no attestation.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of medication, radiology, and laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency

department (POS 21 or 23) during the EHR reporting period.

• *Numerator:* The number of orders in the denominator recorded using CPOE.

• *Threshold:* The resulting percentage must be more than 60 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 medication, laboratory and radiology orders during the EHR reporting period.

To qualify for the exclusion, an EP's total number of medication, laboratory and radiology orders collectively must be less than 100. For example, an EP who writes 75 medication orders, 50 laboratory orders and no radiology orders during the EHR reporting period would not meet the exclusion.

Consolidated Objective: Implement drug-drug and drug-allergy interaction checks.

For Stage 2, we are proposing to make the objective for ''Implement drug-drug and drug-allergy checks'' one of the measures of the core objective for ''Use clinical decision support to improve performance on high-priority health conditions.'' We continue to believe that automated drug-drug and drug-allergy checks provide important information to advise the provider's decisions in prescribing drugs to a patient. Because this functionality provides important clinical decision support that focuses on patient health and safety, we believe it is appropriate to include this functionality as part of the objective for using clinical decision support.

Proposed EP Objective: Generate and transmit permissible prescriptions electronically (eRx).

The use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the EP generates the prescription electronically, Certified EHR Technology can recognize the information and can provide decision support to promote safety and quality in the form of adverse interactions and other treatment possibilities. The Certified EHR Technology can also provide decision support that promotes the efficiency of the health care system by alerting the EP to generic alternatives or to alternatives favored by the patient's insurance plan that are equally effective. Transmitting the prescription electronically promotes efficiency and safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient. This comparison allows for many of the same decision support functions enabled at the generation of the prescription, but bases them on potentially greater information.

We propose to continue to define prescription as the authorization by an EP to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We propose to define a permissible prescription as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–V *http://www.deadiversion.usdoj.gov/schedules/index.html.* Although the Drug Enforcement Administration's (DEA) interim final rule on electronic prescriptions for controlled substances (75 FR 16236) removed the Federal prohibition to electronic prescribing of controlled substances, some challenges remain including more restrictive State law and widespread availability of products both for providers and pharmacies that include the functionalities required by the DEA's regulations. However, as Stage 2 of meaningful use would not go into effect until 2014, it is possible that significant progress in the availability of products enabling the electronic prescribing of controlled substances may occur. We encourage comments addressing the current and expected availability of these products and whether the availability would be sufficient to include controlled substances in the Stage 2 measure for e-Rx or to warrant an additional measure for EPs to choose that would include controlled substance electronic prescriptions in the denominator.

We do not believe that OTC medicines will be routinely electronically prescribed and propose to continue to exclude them from the definition of a prescription. However, we encourage public comment on this assumption.

Several different workflow scenarios are possible when an EP prescribes a drug for a patient. First, the EP could prescribe the drug and provide it to the patient at the same time, and sometimes the EP might also provide a prescription for doses beyond those provided concurrently. Second, the EP could prescribe the drug, transmit it to a pharmacy within the same organization, and the patient would obtain the drug from that pharmacy. Third, the EP could prescribe the drug, transmit it to a pharmacy independent of the EP's organization, and the patient would obtain the drug from that pharmacy. Although each of these scenarios would result in the generation of a prescription, the transmission of the prescription would vary. In the first situation, there is no transmission. In the second situation, the transmission may be the viewing of the generation of the prescription by another person using the same Certified EHR Technology as the EP, or it could be the transmission of the prescription from the Certified EHR Technology used by the EP to another system used by the same organization in the pharmacy. In the third situation, the EP's Certified EHR Technology transmits the prescription outside of their organization either through a third party or directly to the external pharmacy. These differences in transmissions create differences in the need for standards. We propose that only the third situation would require standards to ensure that the transmission meets the goals of electronic prescribing. In the first two scenarios one organization has control over the whole process. In the third scenario, the process is divided between organizations. In that situation, standards can ensure that despite the lack of control the whole process functions reliably. To have successfully e-prescribed, the EP needs to use Certified EHR Technology as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the EP's organization such transmission must use the standards included in certification of EHRs.

We received many inquiries as to the alignment with this objective and the eRx payment adjustment authorized by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The HITECH Act phases out the adjustment starting in CY 2015 so alignment between the programs is no longer necessary. At the time of publication of this proposed rule, the determination for CY 2013 MIPPA eRx payment adjustment will have already occurred. For these reasons alignment with Stage 2 becomes a moot point.

Proposed EP Measures: More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.

In Stage 1 of meaningful use, we adopted a measure of more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using Certified EHR Technology. In the Stage 1 rule (75 FR 44338), we acknowledged that there were reasons why a patient may prefer a paper prescription. A patient could have this preference for any number of reasons such as the desire to shop for

the best price (especially for patients in the Part D ''donut hole''), the ability to obtain medications through the Department of Veterans Affairs, lack of finances, indecision about whether to have the prescription filled locally or by mail order, and desire to use a manufacturer coupon to obtain a discount. We correspondingly lowered the threshold to 40 percent from 75 percent as proposed for Stage 1 to account for patient preference for a paper prescription. While pharmacy acceptance of electronic prescriptions continues to accelerate, these patient preferences remain creating a ceiling for this threshold on which there is limited data with which to estimate.

The HIT Policy Committee recommended an increase in the threshold of this measure from 40 percent to 50 percent. The average successful Medicare meaningful EHR user rate currently exceeds 50 percent demonstrating to us that 50 percent does not exceed the ceiling created by patient preferences. We also believe that providers participating in Stage 2 will already have significant experience with this objective and can meet an even higher threshold. Therefore we are proposing a threshold of 65 percent for this measure.

The ease with which an EP can meet this measure depends heavily on the availability of pharmacies in their local area that accept electronic prescriptions. We propose a new exclusion for Stage 2 that would allow EPs to exclude this objective, if no pharmacies within 25 miles of an EP's practice location at the start of his/her EHR reporting period accept electronic prescriptions. This is 25 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. For EP's practicing at multiple locations, they are eligible for the exclusion if any of their practice locations that are equipped with Certified EHR Technology meet this criteria. An EP would not be eligible for this exclusion if he or she is part of an organization that owns or operates its own pharmacy within the 25-mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization.

We also have considered instances where an EP may prescribe medications in a facility (such as a nursing home or ambulatory surgery center) where they are compelled to use the facility's ordering system, which may not be Certified EHR Technology. While we are not proposing exclusionary criteria related to this circumstance, we encourage comments on whether one is necessary or if the proposed 50 percent threshold is low enough to account for this situation.

The inclusion of the comparison to at least one drug formulary enhances the efficiency of the healthcare system when clinically appropriate and cheaper alternatives may be available. We recognize that not all drug formularies are linked to all Certified EHR Technologies, so we are not requiring that the formulary be relevant for each patient. Therefore, the comparison could return a result of formulary unavailable for that patient and medication combination and still allow the EP to meet the measure of this objective. This modification of the measure replaces the Stage 1 menu objective of ''Implement drug-formulary checks'' and is intended to provide better integration guidance for both EPs and their supporting vendors.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period.
- *Numerator:* The number of prescriptions in the denominator generated, compared to a drug formulary and transmitted electronically.
- *Threshold:* The resulting percentage must be more than 65 percent in order for an EP to meet this measure.

Exclusions: Any EP who writes fewer than 100 prescriptions during the EHR reporting period or does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 miles of the EP's practice location at the start of his/her EHR reporting period.

Consolidated Objective: Maintain an up-to-date problem list of current and active diagnoses.

Consolidated Objective: Maintain active medication list.

Consolidated Objective: Maintain active medication allergy list.

For Stage 2, we are proposing to consolidate the objectives for maintaining an up-to-date problem list, active medication list, and active medication allergy list with the Stage 2 objective for providing a summary of care for each transition of care or referral. We continue to believe that an up-to-date problem list, active medication list, and active medication allergy list are important elements to be maintained in Certified EHR Technology. However, the continued demonstration of their meaningful use in Stage 2 is required by other objectives focused on the transitioning of care of patients removing the necessity of measuring them separately. Providing this information is critical to continuity of care, so we are proposing to add these as required fields in the summary of care for the following Stage 2 objective: ''The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.'' EPs and hospitals would have to ensure the accuracy of these fields when providing the summary of care, which we believe will ensure a high level of compliance in maintaining an up-to-date problem list, active medication list, and active medication allergy list for patients. The required standards for these fields are discussed in the ONC standards and certification proposed rule published elsewhere in this issue of the **Federal Register**.

Proposed EP Objective: Record the following demographics: Preferred language, gender, race and ethnicity, and date of birth.

Proposed Eligible Hospital/CAH Objective: Record the following demographics: Preferred language, gender, race and ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

The recording of demographic data benefits healthcare and population health. Gender, race, ethnicity, and age are all established risk factors for a large number of diseases and conditions. Having this information available to healthcare providers improves their ability to care for individual patients. This same information combined with preferred language and date and cause of death can create revealing data on the health of populations as small as the population treated by a single healthcare provider to the national population. Health disparities can be identified and risk factors for disease and conditions can be identified and refined, among other uses for this data.

In order to obtain these benefits, especially for public health, it is important that information from different sources be comparable. For this reason, we propose to continue the use of the Office of Management and Budget (OMB) standards for race and ethnicity (*http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr*). As outlined in the OMB policy, more detailed descriptions of race can be used, but ultimately would need to be mapped to 1 of the 5 races included in the OMB standards. Current OMB standards align race categories with

every geographic location in the globe so there are not barriers to completing such mapping. We recognize that race is a social construct that varies across cultures and time which is why we fully support the use of other descriptions that can then be mapped using geography constructs to the OMB standards. There must also be the option for the selection of multiple races for a patient and an option for cases when a patient declines to provide the information.

The recording of the cause of death raised many questions from providers in Stage 1 of meaningful use. Some cases are referred to medical examiners to determine the official cause of death while others are not. Individual hospital policies and local/State laws and regulations vary. For purposes of meaningful use, we refer to the preliminary cause of death recorded by the hospital. This preliminary cause is not required to be amended due to additional information, but the hospital may amend the information if they want to maintain the most accurate information. The recording of the preliminary cause of death also does not have to occur within a specified timeframe from the death. We believe these clarifications will enable hospitals to meet this measure, but we encourage comments on our description of recording the cause of death.

In addition, we encourage public comment on the burden and ability of including disability status for patients as part of the data collection for this objective. We believe that the recording of disability status for certain patients can improve care coordination, and so we are considering making the recording of disability status an option for providers. We seek comment on the burden incorporating such an option would impose on EHR vendors, as well as the burden that collection of this data might impose on EPs, eligible hospitals, and CAHs. In addition, we request public comment on—(1) how to define the concept ''disability status'' in this context; and (2) whether the option to collect disability status for patients should be captured under the objective to record demographics, or if another objective would be more appropriate.

We also seek comment on whether, we should also include the recording of gender identity and/or sexual orientation. We encourage commenters to identify the benefits of inclusion and the applicability across providers.

Proposed Measure: More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data.

For Stage 1 of meaningful use, we adopted a measure of more than 50 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data. We agree with the HIT Policy Committee recommendation to increase the threshold of this measure and are proposing a more than 80 percent threshold for Stage 2 of meaningful use. Our experience with Stage 1 shows performance on this measure above 80 percent.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator who have all the elements of demographics (or a specific notation if the patient declined to provide one or more elements or if recording an element is contrary to State law) recorded as structured data.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital or CAH to meet this measure.

If a patient declines to provide one or more demographic elements, this can be noted in the Certified EHR Technology and the EP or hospital may still count the patient in the numerator for this measure. The required elements and standards for recording demographics and noting omissions because of State law restrictions or patients declining to provide information will be discussed in the ONC standards and certification proposed rule, published elsewhere in this issue of the **Federal Register**.

Proposed Objective: Record and chart changes in the following vital signs: Height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0–20 years, including BMI.

Having accurate information on height/length (depending on a patient's age), weight, and blood pressure both on the current condition of the patient and changes over time provide context to a large number and great variety of clinical decisions. By capturing height, weight, and blood pressure in a structured format, EHRs can analyze and display the information without the need for intervention by the provider. The calculation of body mass index and plotting of growth charts are just two examples. The provider need not do anything to calculate BMI or plot a growth chart if height and weight are recorded as structured data because this functionality is included within Certified EHR Technology. Similarly, information on blood pressure provides many opportunities for clinical decision support and the identification of patient education materials. Again, these automated processes can be enabled within Certified EHR Technology simply by recording blood pressure as structured data.

We propose to continue our policy from Stage 1 that height/length, weight, and blood pressure do not each need to be updated by a provider at every patient encounter nor even once per patient seen during the EHR reporting period. For this objective, we are primarily concerned that some information is available to the EP, eligible hospital or CAH, who can then make the determination based on the patient's individual circumstances as to whether height/length, weight, and blood pressure need to be updated. The information can get into the patient's medical record as structured data in a number of ways. Some examples include entry by the EP, eligible hospital, or CAH, entry by someone on the EP, eligible hospital, or CAH's staff, transfer of the information electronically or otherwise from another provider, or entered directly by the patient through a portal or other means. Some of these methods are more accurate than others and it is up to the EP or hospital to determine what level of accuracy is needed for them to provide care to the patient and how best to obtain this information. Any method of obtaining height, weight or blood pressure is acceptable for purposes of this objective as long as the information is recorded as structured data.

We have received continuous feedback during Stage 1 of meaningful use on the appropriate age for collecting these vital signs. In particular, we have heard from numerous health care professionals and associations and the HIT Policy Committee recommended that height/length and weight should not be age-limited and that the limit for blood pressure should be raised to 3 years of age and older in order to align with guidelines and recommendations from other health care associations. We agree with this alignment and propose to remove the height/length and weight age limits and raise the blood pressure limit to 3 years of age and older, but we encourage public comment on the age limitations of vital signs. Age is

determined based on the date when the patient is last seen by the EP or admitted to the inpatient or emergency department of the hospital during the EHR reporting period.

Because we propose to remove the age restrictions on recording height/length and weight, we also propose to remove the age restrictions on calculating and displaying BMI and growth charts.

Proposed Measure: More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

We included two exclusions for EPs for this measure in Stage 1 of meaningful use. The first is that EPs who do not see any patients 2 years old or older (proposed to be raised to 3 years old or older optionally in 2013 and permanently in 2014) are excluded from recording blood pressure. The second is for EPs who believe that all 3 vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice. We received considerable feedback on Stage 1 that many EPs believe that while they may collect weight and blood pressure, they do not believe height/length is relevant to their scope of practice, or that blood pressure is relevant, but not height/length and weight, or some other combination.

Weight without height/length is not useful from a record keeping perspective. A 225 pound man who is 5′5″ has different considerations than a 225 pound man who is 6′5″ . Therefore, we propose to keep the recording of height/length and weight as linked requirements. We believe there are situations where height/length and weight may be relevant, but blood pressure is not. We are less certain that there would be cases where blood pressure is relevant, but height/length and weight are not. We propose for Stage 2 to split the exclusion so that an EP can choose to record height/length and weight only and exclude blood pressure or record blood pressure only and exclude height/length and weight. We encourage comments on this split and whether it should or should not go both ways.

For Stage 1 of meaningful use, we adopted a measure of more than 50 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have vital signs recorded as structured data. We agree with the HIT Policy Committee recommendation to increase the threshold of this measure and are proposing a more than 80 percent threshold for Stage 2 of meaningful use. Our preliminary Stage 1 data shows that the recording of vital signs far exceeded the measure threshold of more than 50 percent, so we are proposing a threshold of 80 percent for this measure for Stage 2 of meaningful use. We will continue to monitor this Stage 1 data as we solicit public comment so that we can determine if the more than 80 percent threshold is appropriate for this measure.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- *Numerator:* Number of patients in the denominator who have at least one entry of their height/length and weight (all ages) and blood pressure (ages 3 and over) recorded as structured data.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: Any EP who sees no patients 3 years or older is excluded from recording blood pressure.

Any EP who believes that all 3 vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them.

An EP who believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure. An EP who believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

Proposed Objective: Record smoking status for patients 13 years old or older.

Accurate information on smoking status provides context to a high number and wide variety of clinical decisions, such as immediate needs for smoking cessation or long-term outcomes for chronic obstructive pulmonary disease. Cigarette smoking is a key component to the current Million Hearts Initiative (*http://millionhearts.hhs.gov*). We do not propose rules on who may record smoking status or how often the record should be updated.

For Stage 2, we propose to limit this measure to those patients 13 years old and older (as we did in Stage 1). We have not observed any significant consensus around when it is appropriate to collect smoking status, regardless of the presence or absence of other risk factors. If commenters disagree with our age limitation, we encourage them to include their reasons for disagreement and any evidence that may be available as to improved consensus among healthcare providers on what age limit is appropriate.

In Stage 1 of meaningful use, we considered whether to expand the collection of information from smoking status to other forms of tobacco use. We continue to believe that there are insufficient electronic standards for collecting information on other types of tobacco use and that situations where a patient might use multiple types of tobacco would damage the standardized collection of smoking data, but we request comment on whether this is the case.

Finally, in Stage 1 of meaningful use, we considered whether to include second hand smoke information as part of this objective. We continue to believe that the level of complexity in introducing this requirement is beyond a reasonable expectation of meaningful use at this time. We believe it would be difficult to define what constitutes a level of exposure to trigger recording second hand smoke information. We encourage commenters to submit information to us that demonstrates consensus and/or standards around the collection of second hand smoking data that would provide the basis on which to create an additional tobacco-related measure that is applicable to all EPs and hospitals.

Proposed Measure: More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.

In Stage 1 of meaningful use, we adopted a measure of more than 50 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have smoking status recorded as structured data. As we discussed in the Stage 1 final rule (75 FR 44344), there were many concerns by commenters over the appropriate age at which to inquire about smoking status. There were also considerable differences among commenters as to what the appropriate inquiry was and what it should have included. Because of these comments, we adopted 50 percent as the measure of this objective. The HIT Policy Committee recommended an increase in the

threshold of this measure from more than 50 percent to more than 80 percent. Our preliminary Stage 1 data shows that the recording of smoking status far exceeded the measure threshold of more than 50 percent, so we are proposing a threshold of 80 percent for this measure for Stage 2 of meaningful use. We will continue to monitor this Stage 1 data as we solicit public comment so that we can determine if the more than 80 percent threshold is appropriate for this measure.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients age 13 or older seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator with smoking status recorded as structured data.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital, or CAH that neither sees nor admits any patients 13 years old or older.

Replaced EP Objective: Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.

Replaced Eligible Hospital/CAH Objective: Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

In addition to the meaningful use core and menu objectives, EPs and hospitals are still required to report clinical quality measures to CMS or the States in order to demonstrate meaningful use of Certified EHR Technology. However, we propose to eliminate these objectives under 42 CFR 495.6 and instead include the reporting of clinical quality measures (CQMs) as part of the definition of ''meaningful EHR user'' under 42 CFR 495.4. For more information about the requirements for reporting clinical quality measures, see section II.B.3. of this proposed rule. As explained in that section, we are proposing to move to electronic reporting of clinical quality measure information. Because the core and menu objectives under § 495.6 are reported through attestation, we believe it makes more sense to separate the reporting of CQMs from the other meaningful use objectives and measures for Stage 2.

Proposed Objective: Use clinical decision support to improve performance on high-priority health conditions.

Clinical decision support at the point of care is an area of health IT in which significant evidence exists for its substantial positive impact on the quality, safety, and efficiency of care delivery. In Stage 1, we specified that the clinical decision support rule should be relevant to the provider's specialty or related to a high clinical priority. We purposely used a description that would allow a provider significant leeway in determining the clinical decision support interventions that are most relevant to their scope of practice and benefit their patients in the greatest way. Following the recommendations of the HIT Policy Committee, we are proposing to modify the objective for Stage 2 to using clinical decision support to improve performance on high-priority health conditions. We believe that it is best left to the provider's clinical discretion to determine which clinical decision support interventions would address high-priority conditions for their individual patient populations, but we are requiring as a measure of this objective that the clinical decision support intervention be related to 5 or more of the clinical quality measures on which EPs or hospitals would be expected to report. We define ''related'' to mean that the intervention's intent is to improve the performance of the EP, eligible hospital, or CAH on a given clinical quality measure. Because clinical quality measures focus on high-priority health conditions by definition, this alignment will ensure that clinical decision support is also focused on high-priority health conditions and improved performance in measurable quality areas.

For Stage 2, we are also proposing to make the Stage 1 objective for ''Implement drug-drug and drug-allergy checks'' one of the measures of this clinical decision support objective. We continue to believe that automated drug-drug and drug-allergy checks provide important information to advise the provider's decisions in prescribing drugs to a patient. Because this functionality provides important clinical decision support that focuses on patient health and safety, we believe it is appropriate to include this functionality as part of this objective for using clinical decision support. Finally, we have replaced the term ''clinical decision support rule'' used in our Stage 1 rule with the term ''clinical decision support intervention'' to better align with, and clearly allow for, the variety of decision support mechanisms available to help improve clinical performance and outcomes. This mirrors an identical change in the ONC Standards and Certification proposed rule.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period.
2. The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

The drug-drug and drug-allergy checks and the implementation of 5 clinical decision support interventions are separate measures for this objective. Therefore the EP or hospital must implement clinical decision support interventions in addition to drug-drug and drug-allergy interaction checks.

For Stage 2 based on the HIT Policy Committee recommendations, each clinical decision support intervention must enable the provider to review all of the following attributes of the intervention: Developer of the intervention, bibliographic citation, funding source of the intervention, and release/revision date of the intervention. This will enable providers to review complete information including any potential conflict of interest for the decision support intervention(s), if they so choose. Certified EHR technology will display these attributes allowing providers to review them. Such information may be valuable so that providers can understand whether the clinical evidence that the intervention represents is current, and whether the development of that intervention was sponsored by an organization that may have conflicting business interests including, but not limited to, a pharmaceutical company, pharmacy benefits management company, or device manufacturer. We believe that there may be cases in which such organizations will have interest in sponsoring clinical decision support interventions, and such interventions may very well be in the patient's best interest. Nonetheless, such sponsorship should be made transparent to the provider using the system.

In addition to the review of clinical decision support attributes, providers must implement the clinical decision support intervention at a relevant point in patient care when the intervention can influence clinical decision making before an action is taken on behalf of the patient. Although we leave it to the provider's clinical discretion to determine the relevant point in patient

care when such interventions will be most effective, the interventions must be presented through Certified EHR Technology to a licensed healthcare professional who can exercise clinical judgment about the decision support intervention before an action is taken on behalf of the patient.

Finally, we propose that clinical decision support intervention must be related to 5 or more of the clinical quality measures that we will finalize for EPs and hospitals and on which they will be expected to report. By relating clinical decision support interventions to one or more clinical quality measures, providers are necessarily focusing on high-priority health conditions, as required by the objective and recommended by the HIT Policy Committee. Providers would implement 5 clinical decision support interventions that they believe will result in improvement in performance for 5 or more of the clinical quality measures on which they report. For example, EPs reporting on the clinical quality measure of ''Preventive Care and Screening: Influenza Immunization for Patients 50 Years Old or Older'' (NQF 0041, PQRI 110) could choose to implement a clinical decision support intervention that triggers an alert in Certified EHR Technology prompting a licensed healthcare professional to ask about influenza immunizations whenever a patient 50 years old or older presents for an office visit or other action that increases the likelihood that the patient receives an influenza immunization.

Please note that for Stage 2, we do not propose to require the provider to demonstrate actual improvement in performance on clinical quality measures. Rather, the provider must use the goal of improvement in performance for a clinical quality measure when the provider selects a clinical decision support intervention to implement. If none of the clinical quality measures are applicable to an EP's scope of practice, the EP should implement a clinical decision support intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care. We believe that the proposed clinical quality measures for eligible hospitals and CAHs would provide ample opportunity for implementing clinical decision support interventions related to high-priority health conditions.

We do not believe that any EP, eligible hospital, or CAH would be in a situation where they could not implement five clinical decision support intervention as previously described. Therefore, we do not propose any exclusions for this objective and its associated measure.

Replaced Objective: Provide patients with an electronic copy of their health information.

Replaced Objective: Provide patients with an electronic copy of their discharge instructions.

For Stage 2, we are not proposing the Stage 1 meaningful use objectives for EPs and hospitals to provide patients with an electronic copy of their health information and discharge instructions upon request. The HIT Policy Committee recommended that these objectives be combined with objectives for online viewing and downloading. We agree with the HIT Policy Committee and are replacing these Stage 1 objectives with proposed objectives and measures for Stage 2 that would enable patients to view online and download their health information and hospital admission information (discussed later in this rule). We believe that continued online access to such information is more useful and provides greater accessibility over time and in different health care environments than a single electronic transmission or a one-time provision of an electronic copy, especially when that access is coupled with the ability to download a comprehensive point in time record.

Proposed EP Objective: Provide clinical summaries for patients for each office visit.

A summary of an office visit provides patients and their families with a record of the visit. This record can prove to be a vital reference for the patient and their caregivers about their health and actions they should be taking to improve their health. Without this reference, the patient must either recall each detail of the visit, potentially missing vital information, or contact the provider after the visit. Certified EHR technology enables the provider to create a summary easily and in many cases instantly. This capability removes nearly all of the barriers that exist when using paper records.

We also note that this is a meaningful use requirement, which does not override an individual's broader right under HIPAA to access his or her health information. Providers must continue to comply with all applicable requirements under the HIPAA Privacy Rule, including the access provisions of 45 CFR 164.524. However, none of the HIPAA access requirements preclude an EP from releasing electronic copies of clinical summaries to their patients as required by this meaningful use provision.

Proposed EP Measure: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

Following the recommendation of the HIT Policy Committee, we propose to continue the 50 percent threshold from Stage 1. Although many EPs provide paper summaries as the patient leaves the office, we believe that a timeframe is still needed for those EPs who provide electronic summaries either as the provider's preferred method of distribution or to accommodate patient requests for electronic summaries. Because the clinical summary is intended to be a summary of clinical information relevant to an office visit, we agree with the HIT Policy Committee that 24 hours is a sufficient timeframe in which to provide this summary. We note that the vast majority of information required in the clinical summary should be immediately available upon completion of the office visit. Although we provided 3 business days to send the clinical summary in Stage 1, we now believe that a faster exchange of information with patient is not only possible but also encourages better quality of care. However, we welcome comments on this timeframe. As in Stage 1, if a paper summary is mailed to the patient, the timeframe relates to when the summary is mailed and not when it is received by the patient.

Summaries of an office visit can quickly become out of date due to information not available to the EP at the end of the visit. The most common example of this is laboratory results. When such information becomes available, the HIT Policy Committee recommended that the EP have 4 business days to make the information known to the patient. We concur that EPs should make this information known to the patient, but do not believe that a new clinical summary must be issued in every instance. For example, current common practice is for laboratory results to be delivered by phone. We are proposing another objective of meaningful use that would provide for online access to the latest health information, whereas this clinical summary objective focuses on a singular visit. We also are concerned with the practicality of measuring this aspect and cannot determine how we would assign a denominator to it. The EHR would have to be capable of recognizing that additional information is available, link such information to a specific office visit, time the provision of information to the patient, and create a record that the patient was notified. We believe that this is too burdensome. The clinical summary would include information on pending tests, and therefore, will alert

patients that more information may soon be available if necessary. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of office visits conducted by the EP during the EHR reporting period.
- *Numerator:* Number of office visits in the denominator where the patient is provided a clinical summary of their visit within 24 hours.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period.

We propose to require the following information to be part of the clinical summary for Stage 2:

- Patient Name.
- Provider's name and office contact information.
- Date and location of the visit.
- Reason for the office visit.
- Current problem list and any updates to it.
- Current medication list and any updates to it.
- Current medication allergy list and any updates to it.
- Procedures performed during the visit.
- Immunizations or medications administered during the visit.
- Vital signs and any updates.
- Laboratory test results.
- List of diagnostic tests pending.
- Clinical instructions.
- Future appointments.
- Referrals to other providers.
- Future scheduled tests.
- Demographics maintained by EP (gender, race, ethnicity, date of birth, preferred language). (New requirement for Stage 2.)
- Smoking status (New requirement for Stage 2.)
- Care plan field, including goals and instructions. (New requirement for Stage 2.)
- Recommended patient decision aids (if applicable to the visit). (New requirement for Stage 2.)

This is not intended to limit the information made available in the clinical summary by the EP. An EP can make available additional information and still meet the objective. The content of the care plan is dependent on the clinical context. We propose to describe a care plan as the structure used to define the management actions for the various conditions, problems, or issues. For purposes of meaningful use measurement, we propose that a care plan must include at a minimum the following components: Problem (the focus of the care plan), goal (the target outcome) and any instructions that the provider has given to the patient. A goal is a defined target or measure to be achieved in the process of patient care (an expected outcome).

We encourage EPs to develop the most robust care plan that is warranted by the situation. We also welcome comments on both our description of a care plan and whether a description is necessary for purpose of meaningful use. When an office visit lasts for several consecutive days and/or the patient is seen by multiple EPs during one office visit, a single consolidated summary at the end of the visit meets this objective. An example of a multiday office visit could be an evaluation one day, a diagnostic test the next and a follow-up treatment the next day based on the results of the test. Even in cases where multiple office visits occur under a global or bundled claim/fee, each visit results in an update to the status of the health of the patient and must be accompanied with a clinical summary.

We would also maintain several other policies from Stage 1. For purposes of meaningful use, an EP may withhold information from the clinical summary if they believe substantial harm may arise from its disclosure through an after-visit clinical summary. An EP can choose whether to offer the summary electronically or on paper by default, but at the patient's request must make the other form available. The EP can select any modality (for example, online, CD, USB) as their electronic option and does not have to accommodate requests for different modalities. We do not believe it would be appropriate for an EP to charge the patient a fee for providing the summary.

When a single consolidated summary is provided for an office visit that lasts for several consecutive days, or for an office visit where a patient is seen by multiple EPs, that office visit must be counted only once in both the numerator and denominator of the measure.

Removed Objective: Capability to exchange key clinical information.

In Stage 2, we propose to move to actual use cases of electronic exchange of health information through the following objective: ''The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.'' We believe that this actual use case is more beneficial and easier to understand. We also propose to remove this objective for Stage 1 as well, but consider other option. Please refer to the section titled ''Changes to Stage 1'' for details of the options considered. As we propose that the EHR reporting period for Stage 2 of meaningful use is the entire year, a prudent provider would be preparing and testing to conduct actual exchange prior to the start of Stage 2 during their Stage 1 EHR reporting periods.

Proposed Objective: Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

Protecting electronic health information is essential to all other aspects of meaningful use. Unintended and/or unlawful disclosures of personal health information could diminish consumers' confidence in EHRs and electronic health information exchange. Ensuring that health information is adequately protected and secured will assist in addressing the unique risks and challenges that may be presented by electronic health records.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.

This measure is the same as in Stage 1 except that we specifically address the encryption/security of data that is stored in Certified EHR Technology (data at rest). Due to the number of breaches reported to HHS involving lost or stolen devices, the HIT Policy Committee recommended specifically highlighting the importance of an entity's reviewing its encryption practices as part of its risk analysis. We agree that this is an area of security that appears to need specific focus. Recent HHS analysis of reported breaches indicates that almost 40 percent of large breaches involve lost or stolen devices. Had these devices been encrypted, their data would have been secured. It is for these reasons that we specifically call out this element of the requirements under 45 CFR 164.308(a)(1) for the meaningful use measure. We do not propose to change the HIPAA Security Rule requirements, or require any more than would be required under HIPAA. We only emphasize the importance of an EP or hospital including in its security risk analysis an assessment of the reasonableness and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and

appropriate, the adoption of an equivalent alternative measure.

We propose this measure because the implementation of Certified EHR Technology has privacy and security implications under 45 CFR 164.308(a)(1). A review must be conducted for each EHR reporting period and any security updates and deficiencies that are identified should be included in the provider's risk management process and implemented or corrected as dictated by that process.

We emphasize that our discussion of this measure and 45 CFR 164.308(a)(1) is only relevant for purposes of the meaningful use requirements and is not intended to supersede what is separately required under HIPAA and other rulemaking. Compliance with the HIPAA requirements is outside of the scope of this rulemaking. Compliance with 42 CFR Part 2 and State mental health privacy and confidentiality laws is also outside the scope of this rulemaking. EPs, eligible hospitals or CAH affected by 42 CFR Part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or State authorities.

(b) Objectives and Measures Carried Over (Modified or Unmodified) from Stage 1 Menu Set to Stage 2 Core Set

We signaled our intent in the Stage 1 final rule to move the objectives from the Stage 1 menu set to the Stage 2 core set. The HIT Policy Committee also recommended that we move all of these objectives to the core set for Stage 2. We propose to include in the Stage 2 core set all of the objectives and associated measures from the Stage 1 menu set, except for the objective ''capability to submit electronic syndromic surveillance data to public health agencies'' for EPs, which would remain in the menu set for Stage 2. As discussed later, we also propose to modify and combine some of these objectives and associated measures for Stage 2.

Consolidated Objective: Implement drug formulary checks.

For Stage 2, we are proposing to include this objective within the core objective for EPs ''Generate and transmit permissible prescriptions electronically (eRx)'' and the menu objective for eligible hospitals and CAHs of ''Generate and transmit permissible discharge prescriptions electronically (eRx).'' We believe that drug formulary checks are most useful when performed in combination with e-prescribing, where such checks can allow the EP or hospital to increase the efficiency of care and benefit the patient financially.

Proposed Objective: Incorporate clinical lab-test results into Certified EHR Technology as structured data.

We believe that incorporating clinical lab-test results into Certified EHR Technology as structured data assists in the exchange of complete information between providers of care, facilitates the sharing of information with patients and their designated representatives, and contributes to the improvement of health care delivery to the patient. We encourage every EP, eligible hospital, and CAH to utilize electronic exchange of results with laboratories in accordance with the certification criteria in the ONC standards and certification proposed rule published elsewhere in this issue of the **Federal Register**. If results are not received through electronic exchange, then they are presumably received in another form (such as by fax, telephone call, mail) and would need to be incorporated into the patient's medical record in some way. We encourage the recording of results as structured data; however, there would be risk of recording the data twice (for example, scanning the faxed results and then entering the results as structured data). To reduce the risk of entry error, we highly encourage the electronic exchange of the results with the laboratory, instead of manual entry through typing, option selecting, scanning or other means.

Proposed Measure: More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data.

Although the HIT Policy Committee did not recommend an increase in the threshold for this measure, our initial data on Stage 1 of meaningful use shows high compliance with this measure for those providers individually selecting the objective from the menu set. Therefore we are proposing to increase the threshold of this objective to 55 percent for Stage 2.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of lab tests ordered during the EHR reporting period by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) whose results are expressed in a positive or negative affirmation or as a number.
- *Numerator:* Number of lab test results whose results are expressed in a positive or negative affirmation or as a number which are incorporated in Certified EHR Technology as structured data.
- *Threshold:* The resulting percentage must be more than 55 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who orders no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period.

There is no exclusion available for eligible hospitals and CAHs because we do not believe any hospital will ever be in a situation where its authorized providers have not ordered any lab tests for admitted patients during an EHR reporting period.

Reducing the risk of entry error is one of the primary reasons we lowered the measure threshold to 40 percent for Stage 1, during which providers are changing their workflow processes to accurately incorporate information into EHRs through either electronic exchange or manual entry. However, for this measure, we do not limit the EP, eligible hospital or CAH to only counting structured data received via electronic exchange, but count in the numerator all structured data. By entering these results into the patient's medical record as structured data, the EP, eligible hospital or CAH is accomplishing a task that must be performed regardless of whether the provider is attempting to demonstrate meaningful use or not. We believe that entering the data as structured data encourages future exchange of information. We have received inquiries on Stage 1 on how to account for laboratory tests that are ordered in a group or panel. The inquiries have highlighted several problems this creates for measurement (for example, EHR only counting a panel as one, but the results individually creating more than 100 percent performance, panels that include tests that are included in the measure and other tests that are not included in the measure, EHRs that count the entire panel if one test meets the numerator criteria). The measure in Stage 1 and Stage 2 counts lab tests individually, not as panels or groups in both the numerator and the denominator for the very complications illustrated by the inquiries that occur when this is not done. However, we solicit comment on whether such individual accounting is infeasible. We note that this in no way precludes the use of grouping and panels when ordering labs. While we are not proposing to move beyond numeric and

yes/no tests, we request comments on whether standards and other capabilities would allow us to expand the measure to all quantitative results (all results that can be compared on as a ratio or on a difference scale).

Proposed Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

Generating patient lists is the first step in proactive management of populations with chronic conditions and is critical to providing accountable care. The ability to look at a provider's entire population or a subset of that population brings insight that is simply not available when looking at patients individually. Small variations that are unnoticeable or seem insignificant on an individual basis can be magnified when multiplied across a population. A number of studies have shown that significant improvements result merely due to provider awareness of population level information. We believe that many EPs and eligible hospitals would use these reports in combination with one of the selected quality measures and decision support interventions to improve quality for a high priority issue (for example, identify patients who are in the denominator for a measure, but not the numerator, and in need of an intervention). The capabilities and variables used to generate the lists are defined in the ONC standards and certification proposed rule published elsewhere in this issue of the **Federal Register**; not all capabilities and variables must be used for every list.

Proposed Measure: Generate at least one report listing patients of the EP, eligible hospital, or CAH with a specific condition.

We propose to continue our Stage 1 policies for this measure. The objective and measure do not dictate the specific report(s) that must be generated, as the EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. The report used to meet the measure can cover every patient or a subset of patients. We believe there is no EP, eligible hospital, or CAH that could not benefit their patient population or a subset of their patient population by using such a report to identify opportunities for quality improvement, reductions in disparities of patient care, or for purposes of research or patient outreach; therefore, we do not propose an exclusion for this measure. The report can be generated by anyone who is on the EP's or hospital's staff during the EHR reporting period. We are also seeking comment on whether a measure that either increases the number and/or frequency of the patient lists would further the intent of this objective.

Proposed EP Objective: Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

By proactively reminding patients of preventive and follow-up care needs, EPs can increase compliance. These reminders are especially beneficial when long time lapses may occur as with some preventive care measures and when symptoms subside, but additional follow-up care is still required.

In Stage 1, this objective was stated as ''Send reminders to patients per patient preference for preventive/follow-up care.'' For Stage 2, the HIT Policy Committee recommended that clinically relevant information from Certified EHR Technology be used to identify patients to whom reminders of preventive/follow-up care would be most beneficial. We agree with this recommendation and are proposing to modify this objective for Stage 2 as ''Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.'' An EP should use clinically relevant information stored within the Certified EHR Technology to identify patients who should receive reminders. We believe that the EP is best positioned to decide which information is clinically relevant for this purpose.

Proposed EP Measure: More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference.

In Stage 1, the measure of this objective was limited to more than 20 percent of all patients 65 years old or older or 5 years old or younger. Rather than raise the threshold for this measure, the HIT Policy Committee recommended lowering the threshold but extending the measure to all active patients. We propose to apply the measure of this objective to all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period. We believe this not only identifies the population most likely to consist of active patients, but also allows the EP flexibility to identify patients within that population who can benefit most from reminders. We encourage comments on the appropriateness of this timeframe. We also recognize that some EPs may not conduct face-to-face encounters with patients but still provide treatment to patients. These EPs could be unintentionally prevented from meeting this core objective under the measure requirements, so we are proposing an exclusion for EPs who have no office visits in order to accommodate such EPs. Patient preference refers to the method of providing the reminder.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients who have had an office visit with the EP in the 24 months prior to the beginning of the EHR reporting period.
- *Numerator:* Number of patients in the denominator who were sent a reminder per patient preference during the EHR reporting period.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

Exclusion: Any EP who has had no office visits in the 24 months before the EHR reporting period.

Proposed EP Objective: Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

The goal of this objective is to allow patients easy access to their health information as soon as possible so that they can make informed decisions regarding their care or share their most recent clinical information with other health care providers and personal caregivers as they see fit. In addition, this objective aligns with the Fair Information Practice Principles (FIPPs),[1] in affording baseline privacy protections to individuals.[2] In particular, the principles include Individual Access (patients should be provided with a

[1] In 1973, the Department of Health, Education, and Welfare (HEW) released its report, *Records, Computers, and the Rights of Citizens,* which outlined a Code of Fair Information Practices that would create ''safeguard requirements'' for certain ''automated personal data systems'' maintained by the Federal Government. This Code of Fair Information Practices is now commonly referred to as fair information practice principles (FIPPs) and established the framework on which much privacy policy would be built. There are many versions of the FIPPs; the principles described here are discussed in more detail in *The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information,* December 15, 2008. *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.*

[2] The FIPPs, developed in the United States nearly 40 years ago, are well-established and have been incorporated into both the privacy laws of many states with regard to government-held records [2] and numerous international frameworks, including the development of the OECD's privacy guidelines, the European Union Data Protection Directive, and the Asia-Pacific Economic Cooperation (APEC) Privacy Framework. *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.*

simple and timely means to access and obtain their individually identifiable information in a readable form and format). This objective replaces the Stage 1 core objective for EPs of ''Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies) upon request'' and the Stage 1 menu objective for EPs of ''Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP.'' The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs, and we agree with their recommendation consistent with our policy of moving Stage 1 menu objectives to the core set for Stage 2. Consistent with the Stage 1 requirements, the patient must be able to access this information on demand, such as through a patient portal or personal health record (PHR). However, providers should be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access there may be patients who cannot access their EHRs electronically because of their disability. Additionally, other health information may not be accessible. Providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

In the Stage 1 final rule (75 FR 44356), we indicated that information should be available to the patient through online access within 4 business days of the information being available to the EP through either the receipt of final lab results or a patient encounter that updates the EP's knowledge of the patient's health. For Stage 2, we propose to maintain the requirement of information being made available to the patient through online access within 4 business days of the information being available to the EP. To that end, we propose to continue the definition of business days as Monday through Friday excluding Federal or State holidays on which the EP or their administrative staff are unavailable. The HIT Policy Committee recommended that EPs be required to make information resulting from a patient encounter available within 24 hours instead of 4 business days. They also recommended continuing the 4 business day timeframe for updates following the receipt of new information. We believe that splitting the timeframes in this manner adds unnecessary complexity to this objective and associated measure. We believe that 4 business days remains a reasonable timeframe and limits the needs for updating. To the extent that Certified EHR Technologies enable a quicker posting time we expect that this will be workflow benefit to the providers and they will utilize this quicker time regardless of the threshold timeline in meaningful use.

Proposed EP Measures: We propose 2 measures for this objective, both of which must be satisfied in order to meet the objective:

1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

2. More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

Transmission can be any means of electronic transmission according to any transport standard(s) (SMTP, FTP, REST, SOAP, etc.). However, the relocation of physical electronic media (for example, USB, CD) does not qualify as transmission although the movement of the information from online to the physical electronic media would be a download.

To calculate the percentage of the first measure for providing patient with timely online access to health information, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.
- *Numerator:* The number of patients in the denominator who have timely (within 4 business days after the information is available to the EP) online access to their health information online.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

To calculate the percentage of the second measure for patients or patient-authorized representatives to view, download or transmit health information, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.
- *Numerator:* The number of unique patients (or their authorized representatives) in the denominator who have viewed online or downloaded or transmitted to a third party the patient's health information.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

Exclusions: Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures. Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude only the second measure.

The thresholds of both of these measures must be reached in order for the EP to meet the objective. If the EP reaches one of these thresholds but not the other, then the EP will fail to meet this objective, unless the EP meets an applicable exclusion. An EP that conducts the 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the second measure. According to the FCC at the time of formulation of this proposed rule, 370 counties in the United States have broadband penetration of less than 50 percent (*www.broadband.gov*). Further discussion of this exclusion can be found under the eligible hospital and CAH objective of ''Provide patients the ability to view online, download, and transmit information about a hospital admission.'' We are also proposing that an EP who neither orders nor creates any of the information listed for inclusion as part of these measures may exclude both the first and second measures.

Consistent with the recommendations of the HIT Policy Committee, we are proposing a threshold of more than 10 percent for patients (or their authorized representatives) to view, download or transmit to a third party health information. An EP has any number of ways to make this information available online. The EP can host a patient portal, contract with a vendor to host a patient portal, connect with an online PHR or other means. As long as the patient can view, download, and transmit the information using a standard web browser and internet connection, the

means is at the discretion of the EP. We note that this new measure does not focus solely on access and instead requires action by patients or their authorized representatives in order for the EP to meet it. A patient who views their information online, downloads it from the internet or uses the internet to transmit it to a third party would count for purposes of the numerator. While this is a departure from most meaningful use measures, which are dependent solely on actions taken by the EP, we believe that requiring a measurement of patient use ensures that the EP will promote the availability and active use of electronic health information by the patient or their authorized representatives. Furthermore, we believe that accountable care should extend to meaningful use objectives that encourage patient and family engagement. We invite comment on this new measure and whether the 10 percent threshold is too high or too low given the patient's role in achieving it.

We define patient-authorized representative as any individual to whom the patient has granted access to their health information. Examples would include family members, an advocate for the patient, or other individual identified by the patient. A patient would have to affirmatively grant access to these representatives with the exception of minors for whom existing local, State or Federal law grants their parents or guardians access without the need for the minor to consent and individuals who are unable to provide consent and where the State appoints a guardian.

In order to make the information available to patients online consistent with the information provided during transitions of care, we are aligning the information required to meet this objective with the information provided in the summary of care record for each transition of care or referral. Therefore, in order to meet this objective, the following information must be made available to patients electronically within 4 business days of the information being made available to the EP:

- Patient name.
- Provider's name and office contact information.
- Problem list.
- Procedures.
- Laboratory test results.
- Medication list.
- Medication allergy list.
- Vital signs (height, weight, blood pressure, BMI, growth charts).
- Smoking status.
- Demographic information (preferred language, gender, race, ethnicity, date of birth).
- Care plan field, including goals and instructions, and
- Any additional known care team members beyond the referring or transitioning provider and the receiving provider.

In circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), the EP may have an indication that the information is not available and still meet the objective and its associated measure.

As stated in the Stage 1 final rule (75 FR 44356), we understand that there may be situations where a provider decides that online posting is not the best forum to communicate results. Within the confines of laws governing patient access to their medical records, we defer to an EP's judgment as to whether to hold information back in anticipation of an actual encounter or conversation between the EP or a member of their staff and the patient. Furthermore, for purposes of meeting this objective, an EP may withhold information from being accessible electronically if its disclosure would cause substantial harm to the patient or another individual. Therefore, if in the EP's judgment substantial harm may arise from the disclosure of particular information, an EP may choose to withhold that particular information. Any such withholding would not affect the EP's ability to meet this measure as that information would not be included in the percentage calculation. However, we note that such withholding of information would not have any effect on a provider's obligations under 45 CFR 164.524 when an individual exercises his or her right of access to inspect and obtain a copy of protected health information about the individual in a designated record set. We do not believe there would be a circumstance where all information about an encounter would be withheld from the patient and therefore some information would be eligible for uploading for online access. If nothing else, information that the encounter occurred should be provided. This is a meaningful use provision, which does not override applicable federal, State or local laws regarding patient access to health information, including the requirements under the HIPAA Privacy Rule at 45 CFR 164.524.

As discussed earlier in this proposed rule, beginning in 2014, Certified EHR Technology will no longer be certified for the Stage 1 objectives of providing patients with an electronic copy of their health information upon request and providing patients with timely electronic access to their health information. This new ''view and download'' objective would replace those objectives, and we are proposing to include it in the core set for Stages 1 and 2 beginning in 2014.'' However, for Stage 1, we are only proposing the first measure of ''More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.'' Both measures would be required for Stage 2.

Proposed Objective: Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

Providing clinically relevant education resources to patients is a priority for the meaningful use of Certified EHR Technology. Because of our experience with this objective in Stage 1, we are clarifying that while Certified EHR Technology must be used to identify patient-specific education resources, these resources or materials do not have to be stored within or generated by the Certified EHR Technology. We are aware that there are many electronic resources available for patient education materials, such as through the National Library of Medicine, that can be queried via Certified EHR Technology (that is, specific patient characteristics are linked to specific consumer health content). The EP or hospital should utilize Certified EHR Technology in a manner where the technology suggests patient-specific educational resources based on the information stored in the Certified EHR Technology. Certified EHR technology is certified to use the patient's problem list, medication list, or laboratory test results to identify the patient-specific educational resources. The EP or hospital may use these elements or additional elements within Certified EHR Technology to identify educational resources specific to patients' needs. The EP or hospital can then provide these educational resources to patients in a useful format for the patient (such as, electronic copy, printed copy, electronic link to source materials, through a patient portal or PHR).

In the Stage 1 final rule (75 FR 44359), we included the phrase ''if appropriate'' in the objective so that the EP or the authorized provider in the hospital could determine whether the education resource was useful and relevant to a specific patient. Consistent with the recommendations of the HIT Policy Committee, we are proposing to remove the phrase ''if appropriate'' from the objective for Stage 2 because we do not believe that any EP or hospital would have difficulty identifying appropriate patient-specific education resources for the low percentage of patients required by the measure of this objective.

We also recognize that providing education materials at literacy levels and cultural competency levels appropriate to patients is an important part of providing patient-specific education. However, we believe that there is not currently widespread availability of such materials and that such materials could be difficult for EPs and hospitals to identify for their patients. We are specifically inviting comments and seeking input on whether EPs and hospitals believe that patient-specific education resources at appropriate literacy levels and with appropriate cultural competencies could be successfully identified at this time through the use of Certified EHR Technology.

Proposed EP Measure: Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP.

In Stage 1, the measure of this objective for EPs was ''More than 10 percent of all unique patients seen by the EP are provided patient-specific education resources.'' Because we are proposing this as a core objective for Stage 2, we have modified the measure for EPs to ''Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP.'' We recognize that some EPs may not conduct face-to-face encounters with patients but still provide treatment to patients. These EPs could be prevented from meeting this core objective under the previous measure requirements, so we are proposing to alter the measure to account for office visits rather than unique patients seen by the EP. We are also proposing an exclusion for EPs who have no office visits in order to accommodate such EPs. The resources would have to be those identified by CEHRT. If resources are not identified by CEHRT and provided to the patient then it would not count in the numerator. We do not intend through this requirement to limit the education resources provided to patient to only those identified by CEHRT. We set the threshold at only ten percent for this reason. We believe that the 10 percent threshold both ensures that providers are using CEHRT to identify patient-specific education resources and is low enough to not infringe on the provider's freedom to choose education resources and to which patients these resources will be provided. The education resources would need to be provided prior to the calculation and subsequent attestation to meaningful use.

To calculate the percentage for EPs, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of office visits by the EP during the EHR reporting period.
- *Numerator:* Number of patients who had office visits during the EHR reporting period who were subsequently provided patient-specific education resources identified by Certified EHR Technology.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.

To calculate the percentage for hospitals, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.
- *Numerator:* Number of patients in the denominator who are subsequently provided patient-specific education resources identified by Certified EHR Technology.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

Our explanation of ''patient-specific education resources identified by Certified EHR Technology'' for the EP measure also applies for the hospital measure.

Proposed Objective: The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

Medication reconciliation allows providers to confirm that the information they have on the patient's medication is accurate. This not only assists the provider in their direct patient care, it also improves the accuracy of information they provide to others through health information exchange.

We note that when conducting medication reconciliation during a transition of care, the EP, eligible hospital or CAH that receives the patient into their care should conduct the medication reconciliation. It is for the receiving provider that up-to-date medication information will be most crucial in order to make informed clinical judgments for patient care. We reiterate that the measure of this objective does not dictate what information must be included in medication reconciliation. Information included in the process of medication reconciliation is appropriately determined by the provider and patient. For the purposes of this objective, we propose to maintain the definition of a transition of care as the movement of a patient from one setting of care (for example, a hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another.

For Stage 2, we also propose to maintain the definition of medication reconciliation as the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency, and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider. There are additional resources available that further define medication reconciliation that while not incorporated into meaningful use may be helpful for EPs, eligible hospitals, and CAHs. While we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing medication reconciliation, we also realize it is unlikely that an automated process within the EHR will fully supplant the medication reconciliation conducted between the provider and the patient. Therefore, the electronic exchange of information is not a requirement for medication reconciliation.

While the objective is to conduct medication reconciliation at all relevant encounters, determining which encounters are relevant beyond transitions of care is too subjective to be included in the measure.

Proposed Measure: The EP, eligible hospital or CAH performs medication

reconciliation for more than 65 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

The HIT Policy Committee recommended maintaining this threshold at 50 percent. However, because this measure relates directly to the role of information exchange that we seek to promote through the meaningful use of Certified EHR Technology, we believe that a higher threshold for this measure is appropriate. Although the majority chose to defer this measure in Stage 1, the performance of both EPs and hospitals was well above the Stage 1 threshold. For these reasons we are proposing to raise the threshold of this measure to 65 percent for Stage 2.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of transitions of care during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the receiving party of the transition.
- *Numerator:* The number of transitions of care in the denominator where medication reconciliation was performed.
- *Threshold:* The resulting percentage must be more than 65 percent in order for an EP, eligible hospital or CAH to meet this measure.
- *Exclusion:* Any EP who was not the recipient of any transitions of care during the EHR reporting period.

Proposed Objective: The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

By guaranteeing lines of communication between providers caring for the same patient, all of the providers of care can operate with better information and more effectively coordinate the care they provide. Electronic health records, especially when linked directly or through health information exchanges, reduce the burden of such communication. The purpose of this objective is to ensure a summary of care record is provided to the receiving provider when a patient is transitioning to a new provider or has been referred to another provider while remaining under the care of the referring provider.

The feedback we have received from providers who have met Stage 1 meaningful use requirements has convinced us that the exchange of key clinical information is most efficiently accomplished within the context of providing a summary of care record during transitions of care. Therefore, we are proposing to eliminate the objective for the exchange of key clinical information for Stage 2 and instead include such information as part of the summary of care when it is a part of the patient's electronic record.

In addition the HIT Policy Committee made two separate Stage 2 recommendations for EPs, eligible hospitals, and CAHs to record additional information—

- Record care plan fields, including goals and instructions, for at least 10 percent of transitions of care; and
- Record team member, including primary care practitioner, for at least 10 percent of patients.

We believe that this information is best incorporated as required data within the summary of care record itself. Rather than implement two separate objectives and measures for these recommendations, we are establishing these as required fields along with the summary of care information listed later. The ONC proposed rule on standards and certification includes these as standard fields required to populate the summary of care document so Certified EHR Technology would be able to include this information. We also recognize that a ''care plan'' may require further definition. The content of the care plan is dependent on the clinical context. We propose to describe a care plan as the structure used to define the management actions for the various conditions, problems, or issues. For purposes of meaningful use measurement we propose that a care plan must include at a minimum the following components: problem (the focus of the care plan), goal (the target outcome) and any instructions that the provider has given to the patient. A goal is a defined target or measure to be achieved in the process of patient care (an expected outcome).

We encourage EPs to develop the most robust care plan that is warranted by the situation. We also welcome comments on both our description of a care plan and whether a description is necessary for purpose of meaningful use.

All summary of care documents used to meet this objective must include the following:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Relevant past diagnoses.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI, growth charts).
- Smoking status.
- Demographic information (preferred language, gender, race, ethnicity, date of birth).
- Care plan field, including goals and instructions, and
- Any additional known care team members beyond the referring or transitioning provider and the receiving provider.

In addition, eligible hospitals and CAHs would be required to include discharge instructions.

In circumstances where there is no information available to populate one or more of the fields listed previously, either because the EP, eligible hospital or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the EP, eligible hospital or CAH may leave the field(s) blank and still meet the objective and its associated measure.

In addition, all summary of care documents used to meet this objective must include the following:

- An up-to-date problem list of current and active diagnoses.
- An active medication list, and
- An active medication allergy list.

We encourage all summary of care documents to contain the most recent and up-to-date information on all elements. In order for the summary of care document to count in the numerator of this objective, the EP or hospital must verify these three fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care document. We define problem list as a list of current and active diagnoses. We solicit comment on whether the problem list should be extended to include, ''when applicable, functional and cognitive limitations'' or whether a separate list should be included for functional and cognitive limitations. We define an up-to-date problem list as a list populated with the most recent diagnoses known by the EP or hospital. We define active medication list as a list of medications that a given patient is currently taking. We define active medication allergy list as a list of medications to which a given patient has known allergies. We define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. Information on problems, medications, and medication allergies could be obtained from previous records, transfer of information from

other providers (directly or indirectly), diagnoses made by the EP or hospital, new medications ordered by the EP or in the hospital, or through querying the patient. In the event that there are no current or active diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies, confirmation of no problems, no medications, or no medication allergies would satisfy the measure of this objective. Note that the inclusion and verification of these elements in the summary of care record replaces the Stage 1 objectives for ''Maintain an up-to-date problem list,'' ''Maintain active medication list,'' and ''Maintain active medication allergy list.''

We leave it to the provider's clinical judgment to identify any additional clinical information that would be relevant to include in the summary of care record.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals.

The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.

- *Exclusion:* Any EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period is excluded from both measures.

To calculate the percentage of the first measure, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.
- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care record was provided.
- *Threshold:* The percentage must be more than 65 percent in order for an EP, eligible hospital, or CAH to meet this measure.

If the provider to whom the referral is made or to whom the patient is transitioned has access to the medical record maintained by the referring provider, then the summary of care record would not need to be provided and that patient should not be included in the denominators of the measures of this objective. We believe that different settings within a hospital using Certified EHR Technology would have access to the same information, so providing a clinical care summary for transfers within the hospital would not be necessary.

To calculate the percentage of the second measure, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.
- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care record was electronically transmitted using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender.
- *Threshold:* The percentage must be more than 10 percent in order for an EP, eligible hospital or CAH to meet this measure.

For Stage 2, we are proposing the additional second measure for electronic transmittal because we believe that the electronic exchange of health information between providers will encourage the sharing of the patient care summary from one provider to another and the communication of important information that the patient may not have been able to provide, which can significantly improve the quality and safety of referral care and reduce unnecessary and redundant testing. Use of common standards can significantly reduce the cost and complexity of interfaces between different systems and promote widespread exchange and interoperability. In acknowledgement of this, ONC has included certain transmission protocols in proposed 2014 Edition EHR certification criteria. Please see the ONC proposed rule published elsewhere in this issue of the **Federal Register** for more details.

These protocols will allow every provider with certified electronic health record technology to have the tools in place to share critical information when patients are discharged or referred, representing a critical step forward in exchange and interoperability. Accordingly, we propose to limit the numerator for this second measure to only count electronic transmissions which conform to the transport standards proposed for adoption at 45 CFR 170.202 of the ONC standards and certification criteria rule.

To meet the second measure of this objective a provider must use Certified EHR Technology to create a summary of care document with the required information according to the required standards and electronically transmit the summary of care document using the transport standards to which its Certified EHR Technology has been certified. No other transport standards beyond those proposed for adoption as part of certification would be permitted to be used to meet this measure.

We acknowledge the benefits of requiring the use of consistently implemented transport standards nationwide, but at the same time want to be cognizant of any unintended consequences of this approach. Thus, ONC requests comments on whether equivalent alternative transport standards exist to the ones ONC proposes to exclusively permit for certification. Comments on transports standards should be made to the ONC proposed rule published elsewhere in this issue of the **Federal Register**, while comments on the appropriateness of limiting this measure to only those standards finalized by ONC should be made to this rule. Note, the use of USB, CD–ROM, or other physical media or electronic fax would not satisfy the measures for electronic transmittal of a summary of care record. The required elements and standards of the summary of care document will be discussed in the ONC standards and certification proposed rule published elsewhere in this issue of the **Federal Register**. We are considering, in lieu of requiring solely the transmission capability and transport standard(s) included in a provider's Certified EHR Technology to be used to meet this measure, also permitting a provider to count electronic transmissions in the numerator if the provider electronically transmits summary of care records to support patient transitions using an organization that follows Nationwide Health Information Network (NwHIN) specifications (*http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_nhin_resources/1194*). This could include those organizations that are part of the NwHIN Exchange as well as any organization that is identified through a governance mechanism ONC would establish

through regulation. We request public comment on whether this additional flexibility should be added to our proposed numerator limitations.

Another potential concern could be that another transport standard emerges after CMS' and ONC's rules are finalized that is not adopted in a final rule by ONC as part of certification, but nonetheless accomplishes the objective in the same way. To mitigate this concern, ONC has indicated in its proposed rule that it would pursue an off-cycle rulemaking to add as an option for certification transport standards that emerge at any time after these proposed rules are finalized in order to keep pace with innovation and thereby allow other transport standards to be used and counted as part of this measure's numerator. We solicit comments on how these standards will further the goal of true health information exchange.

Additionally, in order to foster standards based-exchange across organizational and vendor boundaries, we propose to further limit the numerator by only permitting electronic transmissions to count towards the numerator if they are made to recipients that are—(1) not within the organization of the transmitting provider; and (2) do not have Certified EHR Technology from the same EHR vendor.

We propose these numerator limitations because, in collaboration with ONC, our experience has shown that one of the biggest barriers to electronic exchange is the adoption of numerous different transmission methods by different providers and vendors. Thus, we believe that it is prudent for Stage 2 to include these more specific requirements and conformance to open, national standards as it will cause the market to converge on those transport standards that can best and most readily support electronic health information exchange and avoid the use of proprietary approaches that limit exchange among providers. We recognize that because the 2011 Edition EHR certification criteria did not include specific transport standards for transitions of care, some providers and vendors implemented their own methods for Stage 1 to engage in electronic health information exchange, some of which would no longer be an acceptable means of meeting meaningful use if this proposal were finalized.

Therefore, in order to determine a reasonable balance that makes this measure achievable yet significantly advance interoperability and electronic exchange, we solicit comment on the following concerns stakeholders may have relative to the numerator limitations we proposed previously.

We could see a potential concern related to the feasibility of meeting this proposed measure if an insufficient number of providers in a given geographic location (because of upgrade timing or some other factor) have EHR technology certified to the transport standards ONC has proposed to adopt. For example, a city might have had a widely adopted health information exchange organization that still used another standard that those proposed for adoption by ONC. While it is not our intent to restrict providers who are engaged in electronic health information exchange via other transport standards, we believe requiring the use of a consistent transport standard could significantly further our overarching goals for Stage 2.

We recognize that this limitation extends beyond the existing parameters set for Stage 1, which specified that providers with access to the same medical record do not include transitions of care or referrals among themselves in either the denominator or the numerator. We recognize that this limitation could severely limit the pool of eligible recipients in areas where one vendor or one organizational structure using the same EHR technology has a large market share and may make measuring the numerator more difficult. We seek comment on the extent to which this concern could potentially be mitigated with an exclusion or exclusion criteria that account for these unique environments. We believe the limitation on organizational and vendor affiliations is important because even if a network or organization is using the standards, it does not mean that a network is open to all providers. Certain organizations may find benefits, such as competitive advantage, in keeping their networks closed, even to those involved in the care of the same patient. We believe this limitation will help ensure that electronic transmission of the summary of care record can follow the patient in every situation.

Even without the addition of exclusions Certified EHR Technology would need to be able to distinguish between (1) electronic transmissions sent using standards and those that are not, (2) transmission that are sent to recipients with the same organizational affiliation or not, and (3) transmissions that are sent to recipients using the same EHR vendor or not, and ONC will seek comment in their proposed certification rule as to the feasibility of this reporting requirement for certified EHR technologies.

Despite the possible unintended consequences of the parameters we propose for the numerator, we believe that these limitations will help ensure that electronic health information exchange proceeds at the pace necessary to accomplish the goals of meaningful use. We encourage comments on all these points and particularly suggestions that would both push electronic health information exchange beyond what is proposed and minimize the potential concerns expressed previously.

However, we note that electronic transmittal is not a requirement for the first measure to provide a summary of care record. For the first measure, where the electronic transmittal of the summary of care record is not a requirement but an option, a provider is permitted to generate an electronic or paper copy of the summary of care record using the Certified EHR Technology and to document that it was provided to the patient, receiving provider or both. In this case, the use of physical media such as a CD–ROM, a USB or hard drive, or other formats could satisfy the measure of this objective.

The HIT Policy Committee recommended different thresholds for EPs and hospitals for the electronic transmission measure, with a threshold of only 25 instances for EPs. We believe a percentage-based measure is attainable for both EPs and eligible hospitals/CAHs and better reflects the actual meaningful use of technology. It also provides a more level method for measurement across EPs. We encourage comment on whether there are significant barriers in addition to those discussed above to EPs meeting the 10 percent threshold for this measure.

In addition, the HIT Policy Committee recommended maintaining the 50 percent threshold from Stage 1. However, because this measure relates directly to the role of information exchange that we seek to promote through the meaningful use of Certified EHR Technology, we believe that a higher threshold for this measure is appropriate. Although the majority chose to defer this measure in Stage 1, the performance of both EPs and hospitals was well above the Stage 1 threshold. For these reasons we are proposing to raise the threshold of this measure to 65 percent for Stage 2.

The thresholds of both measures must be reached in order for the EP, eligible hospital, or CAH to meet the objective. If the EP, eligible hospital, or CAH reaches one of these thresholds but not the other, then the EP, eligible hospital, or CAH will fail to meet this objective.

(c) Public Health Objectives

Due to similar considerations among the public health objectives, we are discussing them together. Some Stage 2 public health objectives are in the core set while others are in the menu set. Each objective is identified as either core or menu in the below discussion.

- Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.
- Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.
- Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.
- Capability to identify and report cancer cases to a State cancer registry where authorized, and in accordance with applicable law and practice.
- Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

We are proposing the following requirements, which would apply to all of the public health objectives and measures. We propose that actual patient data is required for the meaningful use measures that include ongoing submission of patient data.

There are a growing number of public health agencies partnering with health information exchange (HIE) organizations to facilitate the submission of public health data electronically from EHRs. As we stated in guidance for Stage 1, (see FAQ at: *https://questions.cms.hhs.gov/app/answers/detail/a_id/10764/kw/immunizations*) we clarify that such arrangements with HIE organizations, if serving on the behalf of the public health agency to simply transport the data, but not transforming content or message format (for example, HL7 format), are acceptable for the demonstration of meaningful use. Alternatively, if the intermediary is serving as an extension of the EP, eligible hospital or CAH's Certified EHR Technology and performing capabilities for which certification is required (for example, transforming the data into the required standard), then that functionality must be certified in accordance with the certification program established by ONC.

- An eligible provider is required to utilize the transport method or methods supported by the public health agency in order to achieve meaningful use.
- Unlike in Stage 1, a failed submission would not meet the objective. An eligible provider must either have successful ongoing submission or meet exclusion criteria.
- We expect that CMS, CDC and public health agencies (PHA) will establish a process where PHAs will be able to provide letters affirming that the EP, eligible hospital or CAH was able to submit the relevant public health data to the PHA. This affirmation letter could then be used by the EP, eligible hospital or CAH for the Medicare and Medicaid meaningful use attestation systems, as well as in the event of any audit. We request comments on challenges to implementing this strategy.

We will accept a yes/no attestation and information indicating to which public health agency the public health data were submitted to support each of the public health meaningful use measures.

Where a measure states ''in accordance with applicable law and practice,'' this reflects that some public health jurisdictions may have unique requirements for reporting and that some may not currently accept electronic data reports. In the former case, the proposed criteria for this objective would not preempt otherwise applicable State or local laws that govern reporting. In the latter case, EPs, eligible hospitals and CAHs would be excluded from reporting.

Proposed Objective: Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

This objective is in the Stage 2 core set for EPs, eligible hospitals and CAHs. The Stage 1 objective and measure acknowledged that our nation's public health IT infrastructure is not universally capable of receiving electronic immunization data from Certified EHR Technology, either due to technical or resource readiness. Immunization programs, their reporting providers and federal funding agencies, such as the CDC, ONC, and CMS, have worked diligently since the passage of the HITECH Act in 2009 to facilitate EPs, eligible hospitals and CAHs ability to meet the Stage 1 measure. We propose for Stage 2 to take the next step from testing to requiring actual submission of immunization data. In order to achieve improved population health, providers who administer immunizations must share that data electronically, to avoid missed opportunities or duplicative vaccinations. Stage 3 is likely to enhance this functionality to permit clinicians to view the entire immunization registry/immunization information system record and support bi-directional information exchange.

The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs and hospitals, and we are adopting their recommendation. We agree that the bar for Stage 2 should move from simply testing the electronic submission of immunization data to ongoing submission. We also agree that given the focus on upgrading and enhancing immunization registries' capacity, under CDC's guidance, this measure is sufficiently achievable to warrant its inclusion in the core set of Stage 2 meaningful use measures. However, we specifically invite comment on the challenges that moving this objective from the menu set to the core set would present for EPs and hospitals.

We also propose to modify the Stage 1 objective to add ''except where prohibited'' because we want to encourage all EPs, eligible hospitals, and CAHs to submit electronic immunization data, even when not required by State/local law. Therefore, if they are authorized to submit the data, they should do so even if is not required by either law or practice. There are a few instances where some EPs, eligible hospitals, and CAHs are not authorized or cannot submit to a State/local immunization registry. For example, in sovereign tribal areas that do not permit transmission to an immunization registry or when the immunization registry only accepts data from certain age groups (for example, adults).

Proposed Measure: Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

Exclusions: Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) The EP, eligible hospital or CAH does not administer any of the immunizations to any of the populations for which data is collected by the jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of receiving electronic immunization data in the specific for Certified EHR Technology at the start of their EHR reporting period; or (3) the EP, eligible hospital or CAH operates in a

jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of their EHR reporting period. For the second and third scenarios, there is no exclusion if an entity designated by the immunization registry can receive electronic immunization data submissions. For example, if the immunization registry cannot accept the data directly or in the version of HL7 used by the provider's Certified EHR Technology, but has designated a Health Information Exchange to do so on their behalf, the provider could not claim the 2nd or 3rd exclusions previously noted.

Proposed Eligible Hospital/CAH Objective: Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

This objective is in the Stage 2 core set for eligible hospitals and CAHs. The same rationale for the changes between this proposed objective and that of Stage 1 are discussed earlier under the immunization registry objective. Please refer to that section for details.

Proposed Eligible Hospital/CAH Measure: Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period.

Please refer to the general public health discussion regarding use of intermediaries.

Exclusions: The eligible hospital or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required by ONC for EHR certification at the start of the EHR reporting period.

Proposed Objective: Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

This objective is in the Stage 2 core set for eligible hospitals and CAHs and the Stage 2 menu set for EPs. The Stage 1 objective and measure acknowledged that our nation's public health IT infrastructure is not universally capable of receiving syndromic surveillance data from Certified EHR Technology, either due to technical or resource readiness. Given public health IT infrastructure improvements and new implementation guidance, for Stage 2, we are proposing that this objective and measure be in the core set for hospitals and in the menu set for EPs. It is our understanding from hospitals and the CDC that many hospitals already send syndromic surveillance data. The CDC has issued the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data [*http://www.cdc.gov/ehrmeaningfuluse/Syndromic.html*] as cited in the ONC proposed rule on EHR standards and certification. However, per the CDC and a 2010 survey completed by the Association of State and Territorial Health Officials (ASTHO), very few public health agencies are currently accepting syndromic surveillance data from ambulatory providers, and there is no corresponding implementation guide at the time of this proposed rule. CDC is working with the syndromic surveillance community to develop a new implementation guide for ambulatory reporting of syndromic surveillance information, which it expects will be available in the fall of 2012. We anticipate that Stage 3 might include syndromic surveillance for EPs in the core set if the collection of ambulatory syndromic data becomes a more standard public health practice in the interim.

The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs and hospitals. However, we are not proposing to adopt their recommendation for EPs. We specifically invite comment on the proposal to leave syndromic surveillance in the menu set for EPs, while requiring it in the core set for eligible hospitals and CAHs.

Proposed Measure: Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

Exclusions: Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) The EP is not in a category of providers that collect ambulatory syndromic surveillance information on their patients during the EHR reporting period (we expect that the CDC will be issuing (in Spring 2013) the CDC PHIN Messaging Guide for Ambulatory Syndromic Surveillance and we may rely on this guide to determine which categories of EPs would not collect such information); (2) the eligible hospital or CAH does not have an emergency or urgent care department; (3) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required by ONC for EHR certification for 2014 at the start of their EHR reporting period; or (4) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of accepting the specific standards required for Certified EHR Technology at the start of their EHR reporting period. As was described under the immunization registry measure, the third and fourth exclusions do not apply if the public health agency has designated an HIE to collect this information on its behalf and that HIE can do so in the specific Stage 2 standards and/or the same standard as the provider's Certified EHR Technology. An urgent care department delivers ambulatory care, usually on an unscheduled, walk-in basis, in a facility dedicated to the delivery of medical care, but not classified as a hospital emergency department. Urgent care centers are primarily used to treat patients who have an injury or illness that requires immediate care but is not serious enough to warrant a visit to an emergency department. Often urgent care centers are not open on a continuous basis, unlike a hospital emergency department which would be open at all times.

(d) New Core and Menu Set Objectives and Measures for Stage 2

We are proposing the following objectives for inclusion in the core set for Stage 2: ''Provide patients the ability to view online, download, and transmit information about a hospital admission'' and ''Automatically track medication orders using an electronic medication administration record (eMAR)'' for hospitals; ''Use secure electronic messaging to communicate with patients'' for EPs. We are proposing all other new objectives for inclusion in the menu set for Stage 2. While the HIT Policy Committee recommended making all objectives mandatory and eliminating the menu option, we believe a menu set is necessary for these new menu set objectives in order to give providers an opportunity to implement new technologies and make changes to workflow processes and to provide maximum flexibility for providers in specialties that may face particular challenges in meeting new objectives.

Proposed Objective: Imaging results and information are accessible through Certified EHR Technology.

Making the image that results from diagnostic scans and accompanying information accessible through Certified EHR Technology increases the utility and efficiency of both the imaging technology and the CEHRT. The ability to share the results of imaging scans will likewise improve the efficiency of all

health care providers and increase their ability to share information with their patients. This will reduce the cost and radiation exposure from tests that are repeated solely because a prior test is not available to the provider.

Most of the enabling steps to incorporating imaging relate to the certification of EHR technologies. As with the objective for incorporating lab results, we encourage the use of electronic exchange to incorporate imaging results into the Certified EHR Technology, but in absence of such exchange it is acceptable to manually add the image and accompanying information to Certified EHR Technology.

Proposed Measure: More than 40 percent of all scans and tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through Certified EHR Technology.

For Stage 2, we do not propose the image or accompanying information (for example, radiation dose) be required to be structured data. Images and imaging results that are scanned into the Certified EHR Technology may be counted in the numerator of this measure. We define accessible as either incorporation of the image and accompanying information into Certified EHR Technology or an indication in Certified EHR Technology that the image and accompanying information are available for a given patient in another technology and a link to that image and accompanying information. Incorporation of the image means that the image and accompanying information is stored by the Certified EHR Technology. Meaningful use does not impose any additional retention requirements on the image. A link to the image and accompanying information means that a link to where the image and accompanying information is stored is available in Certified EHR Technology. This link must conform to the certification requirements associated with this objective in the ONC rule. We encourage comments on the necessary level of specification and what those specifications should be to define accessible and what constitutes a direct link.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of scans and tests whose result is one or more image ordered by the EP or by an authorized provider on behalf of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period.
- *Numerator:* The number of results in the denominator that are accessible through Certified EHR Technology.
- *Threshold:* The resulting percentage must be more than 40 percent in order to meet this measure.

Exclusion: Any EP who does not perform diagnostic interpretation of scans or tests whose result is an image during the EHR reporting period.

We also solicit comments on a potential second measure for this objective that would encourage the exchange of imaging and results between providers. We are considering a threshold of 10 percent of all scans and tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period and accessible through Certified EHR Technology also be exchanged with another provider of care. However, we are concerned that this extra measure may be difficult for some EPs to meet and might discourage a significant number of EPs from selecting this objective as part of their menu set. We also solicit comment on whether an exclusion for this second measure should be included for providers who do not typically exchange imaging scans and test results as a normal part of their workflow, and we encourage commenters to provide details about how such an exclusion might be included.

Proposed Objective: Record patient family health history as structured data.

Family health history is a major risk indicator for a variety of chronic conditions for which effective screening and prevention tools are available. Certified EHR technology can use family health history, if captured as structured data, to inform clinical decision support, patient reminders, and patient education. Family health history would also benefit from greater interoperability made possible by EHRs. A family health history is unique to each patient and fairly static over time. Currently, every provider requests this information from the patient in order to obtain it; however, EHRs can allow the patient to contribute directly to the record and allow the record to be shared among providers, thereby greatly increasing the efficiency of collecting family health histories.

The HIT Policy Committee recommended delaying the inclusion of this objective until Stage 3 due to absence of available standards. However, we believe that standards supporting family health history are currently available. We are proposing this as a menu objective for Stage 2.

Proposed Measure: More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

For Stage 2, we do not propose to include the capability to exchange family health history electronically as part of the measure. We do not believe there is sufficient structured data capture of family health history to support such exchange. After Stage 2 increases the capture of family health history in EHRs, we will seek to include exchange with other providers and the patient in Stage 3.

We propose to adopt the definition of first degree relative used by the National Human Genome Research Institute of the National Institutes of Health. A first degree relative is a family member who shares about 50 percent of their genes with a particular individual in a family. First degree relatives include parents, offspring, and siblings. We considered other definitions, including those that address both affinity and consanguinity relationships and encourage comments on this definition. We note that this is a minimum and not a limitation on the health history that can be recorded. We invite comment on the utility of expanding this definition to capture risks associated with social and other environmental determinants.

We do not propose a time limitation on the indication that the family health history has been reviewed. The recent nature of this capability in EHRs will impose a de facto limitation on review to the recent past.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator with a structured data entry for one or more first-degree relatives.
- *Threshold:* The resulting percentage must be more than 20 percent in order to meet this measure.

We are concerned that certain EPs may not be able to meet this measure either due to scope of practice constraints or lack of patient interaction. Therefore, we are proposing an

exclusion to this measure for EPs who have no office visits during the EHR reporting period. We believe that EPs who do not have office visits would not have the face-to-face contact with patients necessary to obtain family health history information. We also believe that EPs who do not have office visits may be unable to obtain family health history information from referring physicians, which could prevent them from being able to meet the measure of this objective. While the exclusion does not relate directly to the denominator, it represents the barriers justifying the exclusion. Furthermore, all office visits would not require updates to family health history.

Exclusion: Any EP who has no office visits during the EHR reporting period.

Proposed EP Objective: Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

Reporting to cancer registries by EPs would address current underreporting of cancer, especially certain types. In the past most cancers were diagnosed and/or treated in a hospital setting and data were primarily collected from this source. However, medical practice is changing rapidly and an increasing number of cancer cases are never seen in a hospital. Data collection from EPs presents new challenges since the infrastructure for reporting is less mature than it is in hospitals. Certified EHR technology can address this barrier by identifying reportable cancer cases and treatments to the EP and facilitating electronic reporting either automatically or upon verification by the EP. We have included this objective to provide more flexibility in the menu objectives that EPs can choose. We believe that cancer reporting could provide many EPs with a meaningful use public health reporting option that is more aligned with their scope of practice.

We include ''except where prohibited and in accordance with applicable law'' because we want to encourage all EPs to submit cancer cases, even in rare cases where they are not required to by State/local law. Legislation requiring cancer reporting by EPs exists in 49 States with some variation in specific requirements, per the 2010 Council of State and Territorial Epidemiologists (CSTE) State Reportable Conditions Assessment (SRCA) (*http://www.cste.org/dnn/ProgramsandActivities/PublicHealthInformatics/StateReportableConditionsQueryResults/tabid/261/Default.aspx*).'' If EPs are authorized to submit, they should do so even if it is not required by either law or practice.

''In accordance with applicable law and practice'' reflects that some public health jurisdictions may have unique requirements for reporting, and that some may not currently accept electronic provider reports. In the former case, the proposed criteria for this objective would not preempt otherwise applicable State or local laws that govern reporting. In the latter case, eligible professionals would be exempt from reporting.

Proposed EP Measure: Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period.

Exclusions: Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat cancer; or (2) the EP operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required under Stage 2 at the beginning of their EHR reporting period.

An EP must either successfully submit or meet 1 of the exclusion criteria.

Proposed EP Objective: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

We believe that reporting to registries is an integral part of improving population and public health. The benefits of this reporting are not limited to cancer reporting. We include cancer registry reporting as a separate objective because it is more mature in its development than other registry types, not because other reporting is excluded from meaningful use. We have included this objective to provide more flexibility in the menu objectives that EPs can choose. We believe that specialized registry reporting could provide many EPs with meaningful use menu option that is more aligned with their scope of practice.

Proposed EP Measure: Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

Exclusions: Any EP that meets at least 1of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat any disease associated with a specialized registry; or (2) the EP operates in a jurisdiction for which no registry is capable of receiving electronic specific case information in the specific standards required under Stage 2 at the beginning of their EHR reporting period.

Proposed EP Objective: Use secure electronic messaging to communicate with patients on relevant health information.

Electronic messaging (for example, email) is one of the most widespread methods of communication for both businesses and individuals. The inability to communicate through electronic messaging may hinder the provider-patient relationship. Electronic messaging is very inexpensive on a transactional basis and allows for communication even when the provider and patient are not available at the same moment in time. The use of common email services and the security measures that may be used when they are sent may not be appropriate for the exchange of protected health information. Therefore, the exchange of health information through electronic messaging requires additional security measures while maintaining its ease of use for communication. While email with the necessary safeguards is probably the most widely used method of electronic messaging, for the purposes of meeting this objective, secure electronic messaging could also occur through functionalities of patient portals, PHRs, or other stand-alone secure messaging applications.

We are proposing this as a core objective for EPs for Stage 2. The additional time made available for Stage 2 implementation makes possible the inclusion of some new objectives in the core set. We chose to identify objectives that address critical priorities of the country's National Quality Strategy (NQS) (*http://www.healthcare.gov/law/resources/reports/quality03212011a.html*), with a focus on one for EPs and one for hospitals.

For EPs, secure electronic messaging is critically important to two NQS priorities—

- Ensuring that each person/family is engaged as partners in their care; and
- Promoting effective communication and coordination of care.

Secure messaging could make care more affordable by using more efficient communication vehicles when appropriate. Specifically, research demonstrates that secure messaging has been shown to improve patient adherence to treatment plans, which reduces readmission rates. Secure messaging has also been shown to increase patient satisfaction with their care. Secure messaging has been named as one of the top ranked features according to patients. Also, despite some trepidation, providers have seen a reduction in time responding to inquires and less time spent on the phone. We specifically seek comment on whether

there may be special concerns with this objective in regards to behavioral health.

Proposed EP Measure: A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen by the EP during the EHR reporting period.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- Denominator: Number of unique patients seen by the EP during the EHR reporting period.
- Numerator: The number of patients in the denominator who send a secure electronic message to the EP using the electronic messaging function of Certified EHR Technology during the EHR reporting period.
- Threshold: The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period.

We note that this new measure requires action by patients in order for the EP to meet it. While this is a departure from most meaningful use measures, which are dependent solely on actions taken by the EP, we believe that requiring a measurement of patient use ensures that the EP will promote the availability and active use of secure electronic messaging by the patient. Furthermore, we believe that accountable care should extend to accountability for meaningful use objectives that encourage patient and family engagement. We invite comment on this new measure and whether EPs believe that the 10 percent threshold is too high or too low given the patient's role in achieving it.

We specify that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the EP is the best judge of what health information should be considered relevant in this context. We do not specifically include the term ''relevant health information'' in the measure, not because we believe that the messages sent by the patient to the healthcare provider do not need to contain relevant health information, but because we believe the provider is best equipped to determine whether such information is included. It would be too great a burden for the certified EHR technology, or the attestation process, to determine whether the information in the secure message has such information. We also note that there is an expectation that the EP would respond to electronic messages sent by the patient, although we do not specify the method of response or require the EP to document his or her response as a condition of meeting this measure.

To address some circumstances regarding scope of practice, we propose an exclusion to this objective for EPs who have no office visits during the EHR reporting period. Not having any office visits for an entire EHR reporting period indicates that there may not be a need for follow-up communication through secure electronic messaging.

Proposed Eligible Hospital/CAH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

eMAR increases the accuracy of medication administration thereby increasing both patient safety and efficiency. The HIT Policy Committee has recommended the inclusion of this objective for hospitals in Stage 2, and we are proposing this as a core objective for eligible hospitals and CAHs. The additional time made available for Stage 2 implementation makes possible the inclusion of some new objectives in the core set. eMAR is critically important to making care safer by reducing medication errors which may make care more affordable. eMAR has been shown to lead to significant improvements in medication-related adverse events within hospitals with associated decreases in cost. eMAR cuts in half the adverse drug event (ADE) rates for non-timing medication errors, according to a study published in the *New England Journal of Medicine* (Poon et al., 2010, Effect of Bar-Code Technology on the Safety of Medication Administration *http://www.nejm.org/doi/abs/10.1056/NEJMsa0907115?query=NC*). A study done to evaluate cost-benefit of eMAR (Maviglia et al., 2007, Cost-Benefit Analysis of a Hospital Pharmacy Bar Code Solution *http://archinte.ama-assn.org/cgi/content/full/167/8/788*) demonstrated that associated ADE cost savings allowed hospitals to break even after 1 year and begin reaping cost savings going forward.

We propose to define eMAR as technology that automatically documents the administration of medication into Certified EHR Technology using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding). The specific characteristics of eMAR for the EHR Incentive Programs will be further described in the ONC standards and certification criteria proposed rule published elsewhere in this issue of the **Federal Register**.

By its very definition, eMAR occurs at the point of care so we do not propose additional qualifications on when it must be used or who must use it.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR.

This recommendation by the HIT Policy Committee was that the measure of this objective be that eMAR is implemented and in use for the entire EHR reporting period in at least one ward/unit of the hospital. However, we recognize that it may be difficult to provide a definition of ward or unit that is applicable for all eligible hospitals and CAHs. Therefore we are proposing a percentage-based measure that would be applicable to all medication orders created by authorized providers of an inpatient or emergency department. We believe the low threshold of 10 percent allows eligible hospitals and CAHs maximum flexibility in how they choose to implement eMAR. We note that this approach does not prevent an eligible hospital or CAH from implementing eMAR in a single ward or unit, provided that they are able to meet the 10 percent threshold from orders tracked through eMAR in that unit. Eligible hospitals and CAHs might also elect to implement eMAR more widely in order to better complement their current workflow.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of medication orders created by authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of orders in the denominator tracked using eMAR.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

Proposed Eligible Hospital/CAH Objective: Generate and transmit permissible discharge prescriptions electronically (eRx)

The use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the hospital generates the prescription electronically, Certified EHR Technology can recognize the information and can provide decision

support to promote safety and quality in the form of adverse interactions and other treatment possibilities. The Certified EHR Technology can also provide decision support that promotes the efficiency of the health care system by alerting the EP to generic alternatives or to alternatives favored by the patient's insurance plan that are equally effective. Transmitting the prescription electronically promotes efficiency and safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient. This comparison allows for many of the same decision support functions enabled at the generation of the prescription, but bases them on potentially greater information.

The HIT Policy Committee recommended the inclusion of eRx for hospitals for discharge medications. We agree that eRx has unique advantages for discharge medications versus medications dispensed within the hospital. Primarily the efficiency of the transmission and the information it provides to the external pharmacy and/or third party to compare to other medication orders received for the patient.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.

The HIT Policy Committee recommended that this measure be limited to new or changed prescriptions that were ordered during the course of treatment of the patient while in the hospital. The limitation is necessary because prescriptions that originate prior to the hospital stay, and that remain unchanged, would be within the purview of the original prescriber, and not hospital staff or attending physicians. We propose to include this limitation as we agree with the HIT Policy Committee that the hospital would not issue refills for medications they did not authorize or alter during their treatment of the patient. We ask that commenters consider whether a hospital issues refills to patients being discharged for medications the patient was taking when they arrived at the hospital and, if so, whether distinguishing those prescriptions from new or altered prescriptions is unnecessarily burdensome for the hospital.

As this would be a new menu objective for hospitals for Stage 2 and we continue to have concerns about the effect of patient preferences, we are proposing a threshold of 10 percent as recommended by the HIT Policy Committee. We do not believe that an exclusion based on the number of medications is necessary, as we cannot envision a hospital with fewer than 100 prescriptions, but we do propose an exclusion if there are no pharmacies that accept electronic prescriptions within 25 miles of the hospital. A hospital with an internal pharmacy that can dispense these electronic prescriptions to patients after discharge could not qualify for this exclusion.

The inclusion of the comparison to at least one drug formulary enhances the efficiency of the healthcare system when clinically appropriate and cheaper alternatives may be available. Not all drug formularies are linked to all Certified EHR Technologies, so we do not require that the formulary be one that is relevant for the particular patient. Therefore, the comparison could return a result of formulary unavailable for that patient and medication combination. This modification of the measure replaces the Stage 1 menu objective of ''Implement drug-formulary checks'' and is intended to provide better integration guidance both for the hospital and their supporting vendors. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.
- *Numerator:* The number of prescriptions in the denominator generated, compared to a drug formulary and transmitted electronically.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 25 miles at the start of their EHR reporting period.

Proposed Eligible Hospital/CAH Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission.

Studies have found that patients engaged with computer based information sources and decision support show improvement in quality of life indicators, patient satisfaction and health outcomes. (Ralston, Carrell, Reid, Anderson, Moran, & Hereford, 2007) (Gustafson, Hawkins, Bober, S, Graziano, & CL, 1999) (Riggio, Sorokin, Moxey, Mather, Gould, & Kane, 2009) (Gustafson, et al., 2001). In addition, this objective aligns with the FIPPs,[3] in affording baseline privacy protections to individuals. We believe that this information is integral to the Partnership for Patents initiative and reducing hospital readmissions. While this objective does not require all of the information sources and decision support used in these studies, having a set of basic information available advances these initiatives. The ability to have this information online means it is always retrievable by the patient, while the download function ensures that the patient can take the information with them when secure internet access is not available. However, providers should be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access, there may be patients who cannot access their EHRs electronically because of their disability. Additionally, other health information may not be accessible. Providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

We propose this as a core objective for hospitals in Stage 2 with the following information that must be available as part of the objective:

- Admit and discharge date and location.
- Reason for hospitalization.
- Providers of care during hospitalization.
- Problem list maintained by the hospital on the patient.
- Relevant past diagnoses known by the hospital.
- Medication list maintained by the hospital on the patient (both current admission and historical).
- Medication allergy list maintained by the hospital on the patient (both current admission and historical).
- Vital signs at discharge.
- Laboratory test results (available at time of discharge).
- Care transition summary and plan for next provider of care (for transitions other than home).
- Discharge instructions for patient, and
- Demographics maintained by hospital (gender, race, ethnicity, date of birth, preferred language, smoking status).

This is not intended to limit the information made available by the

[3] *Ibid.*

hospital. A hospital can make available additional information and still align with the objective.

A hospital has any number of ways to make this information available online. The hospital can host a patient portal, contract with a vendor to host a patient portal, connect with an online PHR, or other means. As long as the patient can view and download the information using a standard Web browser and internet connection, the means is at the discretion of the hospital.

Proposed Measure: There are 2 measures for this objective, both of which must be satisfied in order to meet the objective.

More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download, or transmit to a third party their information during the EHR reporting period.

This objective replaces two Stage 1 objectives for providing patients electronic copies of their health information upon request and providing electronic copies of discharge instructions. In Stage 1 of meaningful use, there was a measure of 50 percent of patients requesting electronic copies (within 3 business days) and discharge instructions (at time of discharge) were provided to them. The creation of this Stage 2 combined objective creates different time constraints. The HIT Policy Committee recommended 36 hours from discharge as an appropriate time period to meet this measure. We see no compelling reason to alter this recommendation; however, we encourage comment on whether this is an appropriate time frame for this new measure.

The second measure represents a new concept for meaningful use criteria, because it measures the hospital based upon the actions of the patient. The HIT Policy Committee noted that providers would want flexibility with respect to the type of guidance provided to patients. In turn, the HIT Policy Committee recommended best practice guidance for providers, vendors, and software developments. We believe the hospital can sponsor education and awareness activities that result in patients viewing their information. Also, the low threshold of 10 percent recognizes that this kind of measure is in its earlier stages. A patient who views their information online, downloads it from the internet or uses the internet to transmit it to a third party would count for purposes of the numerator. However, we recognize, that in areas of the country where a significant section of the patient population does not have access to broadband internet, this measure may be significantly harder or impossible to achieve. For example, for a hospital in an area with 100 percent broadband availability, only 10 percent of the patient population must view the information. However, a hospital in an area with 30 percent broadband availability must essentially have a third of their patient population view the information. In addition, areas with high broadband penetration tend to correlate with more prolific users making it more likely that patients will view information online. There are 2 possible solutions to this disparity. The first is to exclude hospitals that operate in areas with below a certain threshold of broadband penetration. The second would be to change the measure to 10 percent of the broadband penetration. According to the FCC, 370 counties in the United States have broadband penetration of less than 50 percent (*www.broadband.gov*). Hospitals in areas of low broadband availability tend to service large areas that may extend beyond the county in which the hospital is located. Under the first option we considered, if the county in which the hospital is located has less than 50 percent of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period, the hospital may exclude the second measure. Under the second option, the hospital would have to meet 10 percent of the broadband availability according to the FCC in the county in which they are located at the beginning of the EHR reporting period. For example, if the reported availability in a county on October 1, 2014, for a hospital was 23 percent, the hospital's threshold for the second measure would be 2.3 percent. There are counties currently with zero percent availability. If there is a hospital in a county with zero percent availability, those hospitals would not have to meet the second measure. We propose to adopt the first method as we believe the second method is too complex to be a practical requirement. However, we welcome comments on both options as well as the correct threshold for the first option.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

First Measure:

- Denominator: Number of unique patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator whose information is available online within 36 hours of discharge.
- Threshold: The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

Second Measure:

- Denominator: Number of unique patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator who view, download or transmit to a third party the information provided by the eligible hospital or CAH online during the EHR reporting period.
- Threshold: The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

Exclusion: Any eligible hospital or CAH will be excluded from the second measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period is excluded from the second measure.

(e) Objective and Measure Carried Over Unmodified From Stage 1 Menu Set to Stage 2 Menu Set

Proposed Eligible Hospital/CAH Objective: Record whether a patient 65 years old or older has an advance directive.

The HIT Policy Committee recommended making this a core objective and also requiring eligible hospitals and CAHs to either store an electronic copy of the advance directive in the Certified EHR Technology or link to an electronic copy of the advance directive. However, we propose to maintain this objective as part of the Menu Set and we are not proposing a copy or link to the advance directive for eligible hospitals and CAHs in Stage 2. As we stated in our Stage 1 final rule (75 FR 44345), we have continuing concerns that there are potential conflicts between storing advance directives and existing State laws. Also, we believe that because of State law restrictions, an advance directive stored in an EHR may not be actionable. Finally, we believe that eligible hospitals and CAHs may have other methods of satisfying the intent of this objective at this time, although we recognize that these

workflows may change as EHR technology develops and becomes more widely adopted. Therefore, we do not propose to adopt the HIT Policy Committee's recommendations to require this objective as a core measure, to store an electronic copy of the advance directive in the Certified EHR Technology, or to link to an electronic copy of the advance directive.

The HIT Policy Committee has also recommended the inclusion of this objective for EPs in Stage 2. In our Stage 1 final rule (75 FR 44345), we indicated our belief that many EPs would not record this information under current standards of practice and would only require information about a patient's advance directive in rare circumstances. We continue to believe this is the case and that creating a list of specialties or types of EPs that would be excluded from the objective would be too cumbersome and still might not be comprehensive. Therefore, we are not proposing the recording of the existence of advance directives as an objective for EPs in Stage 2. However, we invite public comment on this decision and encourage commenters to address specific concerns regarding scope of practice and ease of compliance for EPs. And we note that nothing in this rule compels the use of advance directives.

Proposed Eligible Hospital/CAH Measure: More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.

We propose that the measure of this objective would remain unmodified from Stage 1. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients age 65 or older admitted to an eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator who have an indication of an advance directive status entered using structured data.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

Exclusion: Any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

Please note that the calculation of the denominator for the measure of this objective is limited to unique patients age 65 or older who are admitted to an eligible hospital's or CAH's inpatient department (POS 21). Patients admitted to an emergency department (POS 23) should not be included in the calculation. As we discussed in our Stage 1 final rule (75 FR 44345), we believe that this information is a level of detail that is not practical to collect on every patient admitted to the eligible hospital's or CAH's emergency department, and therefore, have limited this measure only to the inpatient department of the hospital.

(f) Other HIT Policy Committee Recommended Objectives Not Proposed

We are not proposing these objectives for Stage 2 as explained at each objective, but we encourage comments on whether these objectives should be incorporated into Stage 2.

Hospital Objective: Provide structured electronic lab results to eligible professionals.

Hospital Measure: Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for more than 40 percent of electronic lab orders received.

The measure for this objective recommended by the HIT Policy Committee is that 40 percent of clinical lab test results electronically sent by an eligible hospital or CAH would need to be done so using the capabilities Certified EHR Technology. This measure requires that in situations where the electronic connectivity between an eligible hospital or CAH and an EP is established, the results electronically exchanged are done so using Certified EHR Technology. To facilitate the ease with which this electronic exchange may take place, ONC has proposed that for certification, ambulatory EHR technology would need to be able to incorporate lab test results formatted in the same standard and implementation specifications to which inpatient EHR technology would need to be certified as being able to create. However, we are not proposing this objective for a variety of reasons. While ONC is working to ease the barriers to this exchange through certification, this assumes that over 40 percent of the ordering providers would be utilizing Certified EHR Technology. Also, as discussed elsewhere, there is more to exchange than the established standards. Secondly, although hospital labs supply nearly half of all lab results to EPs, they are not the predominant vendors for providers who do not share or cannot access their technology. Independent and office laboratories provide over half of the labs in this market. We are concerned that imposing this requirement on hospital labs would unfairly disadvantage them in this market. Furthermore, not all hospitals offer these services so it would create a natural disparity in meaningful use between those hospitals offering these services and those that do not. Finally, all other aspects of meaningful use in Stage 1 and Stage 2 focuses on the inpatient and emergency departments of a hospital. This objective is not related to these departments, in fact, it explicitly excludes services provided in these departments. We encourage comments on both the pros and cons of this objective and whether it should be considered for the final rule as recommended by the HIT Policy Committee. The HIT Policy Committee recommended this as a core objective for Stage 2 for eligible hospitals.

EP Objective/Measure: Record patient preferences for communication medium for more than 20 percent of all unique patients seen during the EHR reporting period.

We believe that this requirement is better incorporated with other objectives that require patient communication and is not necessary as a standalone objective.

Objective/Measure: Record care plan goals and patient instructions in the care plan for more than 10 percent of patients seen during the reporting period.

We believe that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Objective/Measure: Record health care team members (including at a minimum PCP, if available) for more than 10 percent of all patients seen during the reporting period; this information can be unstructured.

We believe that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Objective/Measure: Record electronic notes in patient records for more than 30 percent of office visits.

While we believe that medical evaluation entries by providers are an important component of patient records that can provide information not otherwise captured within standardized fields, we believe there is evidence to suggest that electronic notes are already widely used by providers of Certified EHR Technology and therefore do not need to be included as a meaningful use objective. For example, a 2008 survey of healthcare professionals indicated that 75 percent of respondents were already using an EHR for physician charting/

documentation and 74 percent were already using the EHR for nursing charting/documentation (2008 HIMSS/HIMSS Analytics Ambulatory Healthcare IT Survey: *http://www.himss.org/content/files/2008_HA_HIMSS_ambulatory_Survey.pdf*). However, we note that ONC has included in its Stage 2 proposed rule certification capabilities that require Certified EHR Technology to allow the inclusion of electronic notes that are text-searchable.

Table 4 provides a summary of stage 2 objectives and measures that we are proposing to adopt.

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TABLE 4: STAGE 2 MEANINGFUL USE OBJECTIVES AND ASSOCIATED MEASURES SORTED BY CORE AND MENU SET

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
CORE SET			
Improving quality, safety, efficiency, and reducing health disparities	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.	More than 60 percent of medication, laboratory, and radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.
	Generate and transmit permissible prescriptions electronically (eRx)		More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.
	Record the following demographics • Preferred language • Gender • Race • Ethnicity • Date of birth	Record the following demographics • Preferred language • Gender • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI	Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI	More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	More than 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data
	Use clinical decision support to improve performance on high-priority health conditions	Use clinical decision support to improve performance on high-priority health conditions	1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. 2. The EP, eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entre EHR reporting period.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	Incorporate clinical lab-test results into Certified EHR Technology as structured data	Incorporate clinical lab-test results into Certified EHR Technology as structured data	More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23 during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.
	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care		More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference
		Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)	More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR..

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
Engage patients and families in their health care	Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.		1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information 2. More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download , or transmit to a third party their health information
		Provide patients the ability to view online, download, and transmit information about a hospital admission	1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period
	Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient	Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient	Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP. More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient- specific education resources identified by Certified EHR Technology
	Use secure electronic messaging to communicate with patients on relevant health information		A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen during the EHR reporting period
Improve care coordination	The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 65 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	**Eligible Hospitals and CAHs**	
	The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.	1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals. 2. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.
Improve population and public health	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period
		Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period as authorized.
		Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
Ensure adequate privacy and security protections for personal health information	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.
Menu Set			
Improving quality, safety, efficiency, and reducing health disparities		Record whether a patient 65 years old or older has an advance directive	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.
	Imaging results and information are accessible through Certified EHR Technology.	Imaging results and information are accessible through Certified EHR Technology.	More than 40 percent of all scans and tests whose result is an image ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology
	Record patient family health history as structured data	Record patient family health history as structured data	More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
		Generate and transmit permissible discharge prescriptions electronically (eRx)	More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology
Improve Population and Public Health	Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice		Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period
	Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period
	Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period

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B. Reporting on Clinical Quality Measures Using Certified EHR Technology by Eligible Professionals, Eligible Hospitals, and Critical Access Hospitals

1. Time Periods for Reporting Clinical Quality Measures

This section clarifies the time periods as they relate to reporting clinical quality measures only. We are not proposing any changes to the time periods for reporting clinical quality measures. The EHR reporting period for clinical quality measures under the EHR Incentive Program is the period during which data collection or measurement for clinical quality measures occurs. The reporting period is consistent with our Stage 1 final rule (75 FR 44314) and will continue to track with the EHR reporting periods for the meaningful use criteria:

- Eligible Professionals (EPs): January 1 through December 31 (calendar year).
- Eligible Hospitals and Critical Access Hospitals (CAHs): October 1 through September 30 (Federal fiscal year).
- EPs, eligible hospitals, and CAHs in their first year of meaningful use for Stage 1, the EHR reporting period would be any continuous 90-day period within the calendar year (CY) or Federal fiscal year (FY), respectively. To avoid a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding any payment adjustment year would have to ensure that the 90-day EHR reporting period ends at least three months before the end of the CY or FY, and that all submission is completed by October 1 or July 1, respectively. For an explanation of the applicable EHR reporting periods for determining the payment adjustments, please see section II.D. of this proposed rule.

TABLE 5—REPORTING ON CLINICAL QUALITY MEASURES USING CERTIFIED EHR TECHNOLOGY BY ELIGIBLE PROFESSIONALS, ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS

Provider type	Reporting period for first year of meaningful use (Stage 1)	Submission period for first year of meaningful use (Stage 1)	Reporting period for subsequent years of meaningful use (Stage 1 and Subsequent Stages)	Submission period for subsequent years of meaningful use (Stage 1 and subsequent stages)
EP	90 consecutive days	Anytime immediately following the end of the 90-day reporting period, but no later than February 28 of the following calendar year.	1 calendar year (January 1–December 31).	2 months following the end of the EHR reporting period (January 1–February 28).
Eligible Hospital/ CAH.	90 consecutive days	Anytime immediate following the end of the 90-day reporting period, but no later than November 30 of the following fiscal year.	1 fiscal year (October1–September 30).	2 months following the end of the EHR reporting period (October 1–November 30).

For example, for an EP, an EHR reporting period would be January 1, 2014 through December 31, 2014 and is the same as CY 2014. If the EP is in his or her first year of Stage 1, the EHR reporting period could be at the earliest from January 1, 2014 through March 31, 2014 and at the latest from October 3, 2014 through December 31, 2014. If the EP is demonstrating meaningful use for the first time in CY 2014, for purposes of avoiding the payment adjustment in CY 2015, the EHR reporting period must end by September 30, 2014.

For an eligible hospital or CAH, an EHR reporting period would be October 1, 2013 through September 30, 2014 and is the same as FY 2014. If the eligible hospital or CAH is in its first year of meaningful use for Stage 1, the EHR reporting period could be at the earliest from October 1, 2013 through December 29, 2013 and at the latest from July 3, 2014 through September 30, 2014. If an eligible hospital is demonstrating meaningful use for the first time in FY 2014, for purposes of avoiding the payment adjustment in FY 2015, the EHR reporting period must end by June 30, 2014.

For EPs, eligible hospitals, and CAHs, the submission period for clinical quality measure data to us generally would be 2 months immediately following the end of the EHR reporting period:

- Eligible Professionals: January 1 through February 28.
- Eligible Hospitals and CAHs: October 1 through November 30.
- EPs, eligible hospitals, and CAHs in their first year of Stage 1 could submit clinical quality measure data anytime after their respective 90-day EHR reporting period up to the end of the 2 months immediately following the end of the CY or FY, respectively. However, for purposes of avoiding the payment adjustments, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their clinical quality measure data no later than October 1 (for EPs) or July 1 (for eligible hospitals) of such preceding year.

Using the same examples for the EHR reporting periods previously for an EP, the submission period for CY 2014 would be January 1, 2015 through February 28, 2015. If the EP is in his or her first year of Stage 1, the submission period could begin at the earliest April 1, 2014 and would end February 28, 2015. However, if the EP is demonstrating meaningful use for the first time in CY 2014, for purposes of avoiding the payment adjustment in CY 2015, the clinical quality measure data must be submitted by October 1, 2014.

Using the same examples for the EHR reporting periods previously for an eligible hospital and CAH, the submission period for FY 2014 would be October 1, 2014 through November 30, 2014. If the eligible hospital and CAH is in its first year of Stage 1, the submission period could begin at the earliest December 30, 2013 and would end November 30, 2014. However, if an eligible hospital is demonstrating meaningful use for the first time in FY 2014, for purposes of avoiding the payment adjustment in FY 2015, the clinical quality measure data must be submitted by July 1, 2014.

2. Certification Requirements for Clinical Quality Measures

The Office of the National Coordinator (ONC) sets the certification

criteria for EHR technology, which for clinical quality measures are described in 45 CFR 170.314(c) in ONC's proposed rule published elsewhere in this issue of the **Federal Register**. Certified EHR Technology will be required for the reporting methods finalized from this proposed rule. This may include attestation, reporting under the PQRS EHR reporting option, the group reporting options for EPs, the aggregate portal-based reporting methods, and the finalized reporting method for eligible hospitals and CAHs. Readers should refer to ONC's proposed rule for an explanation of the definition of Certified EHR Technology that would apply beginning with 2014.

In addition, for attestation and the aggregate portal-based reporting methods for EPs, eligible hospitals and CAHs, Certified EHR Technology must be certified to ''incorporate and calculate'' in accordance with 45 CFR 170.314(c)(2) for each individual clinical quality measure that an EP, eligible hospital or CAH submits. EPs, eligible hospitals and CAHs must only submit clinical quality measures that their Certified EHR Technology is explicitly certified to calculate according to 45 CFR 170.314(c)(2) in ONC's proposed rule in order to meet the meaningful use requirement for reporting clinical quality measures. For example, if an EP's Certified EHR Technology is only certified to calculate clinical quality measures #1 through #12, and the EP submits clinical quality measures #1 through #11 and #37, the EP would not have met the meaningful use requirement for reporting clinical quality measures because his/her Certified EHR Technology was not certified to calculate clinical quality measure #37.

Likewise, for attestation and the aggregate portal-based reporting methods, Certified EHR Technology must be certified for ''reporting'' (please refer to the discussion of 45 CFR 170.314(c)(3) in ONC's proposed rule), which certifies the capability to create and transmit a standard aggregate XML-based file that can be electronically accepted by CMS.

3. Criteria for Selecting Clinical Quality Measures

We are soliciting comment on a wide ranging list of 125 potential measures for EPs and 49 potential measures for eligible hospitals and CAHs. We expect to finalize only a subset of these proposed measures.

We are committed to aligning quality measurement and reporting among our programs (for example, IQR, PQRS, CHIPRA, ACO programs). Our alignment efforts focus on several fronts including choosing the same measures for different program measure sets, standardizing measure development and specification processes across CMS programs, coordinating quality measurement stakeholder involvement efforts and opportunities for public input, and identifying ways to minimize multiple submission requirements and mechanisms. For example, we are working towards allowing CQM data submitted via certified EHRs by EPs and EHs/CAHs to apply to other CMS quality reporting programs. A longer term vision would be hospitals and clinicians reporting through a single, aligned mechanism for multiple CMS programs. We believe the alignment options for PQRS/EHR Incentive Program proposed in this rule are the first step towards such a vision. We are exploring how intermediaries and State Medicaid Agencies could participate in and further enable these quality measurement and reporting alignment efforts, while meeting the needs of multiple Medicare and Medicaid programs (for example, ACO programs, Dual Eligible initiatives, Medicaid shared savings efforts, CHIPRA and ACA measure sets, etc). This would lessen provider burden and harmonize with our data exchange priorities, while also supporting our goal of the programs transforming our system to provide higher quality care, better health outcomes, and lower cost through improvement.

In addition to statutory requirements for EPs (section II.B.4.(a) of this proposed rule), eligible hospitals (section II.B.6.(a) of this proposed rule), and CAHs (section II.B.6.(a) of this proposed rule), we relied on the following criteria to select this initial list of proposed clinical quality measures for EPs, eligible hospitals, and CAHs:

- Measures that can be technically implemented within the capacity of the CMS infrastructure for data collection, analysis, and calculation of reporting and performance rates. This includes measures that are ready for implementation, such as those with developed specifications for electronic submission that have been used in the EHR Incentive Program or other CMS quality reporting initiatives, or that will be ready soon after the expected publication of the final rule in 2012. This also includes measures that can be most efficiently implemented for data collection and submission.
- Measures that support CMS and HHS priorities for improved quality of care for people in the United States, which are based on the March 2011 report to Congress, ''National Strategy for Quality Improvement in Health Care'' (National Quality Strategy) (*http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf*) and the Health Information Technology Policy Committee's (HITPC's) recommendations (*http://healthit.hhs.gov/portal/server.pt?open=512&objID=1815&parentname=CommunityPage&parentid=7&mode=2&in_hi_userid=11113&cached=true*). These include the following 6 priorities:
  - ++ Making care safer by reducing harm caused in the delivery of care.
  - ++ Ensuring that each person and family are engaged as partners in their care.
  - ++ Promoting effective communication and coordination of care.
  - ++ Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
  - ++ Working with communities to promote wide use of best practices to enable healthy living.
  - ++ Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.
- Measures that address known gaps in quality of care, such as measures in which performance rates are currently low or for which there is wide variability in performance, or that address known drivers of high morbidity and/or cost for Medicare and Medicaid.
- Measures that address areas of care for different types of eligible professionals (for example, Medicare- and Medicaid-eligible physicians, and Medicaid-eligible nurse-practitioners, certified nurse-midwives, dentists, physician assistants).

In an effort to align the clinical quality measures used within the EHR Incentive Program with the goals of CMS and HHS, the National Quality Strategy, and the HITPC's recommendations, we have assessed all proposed measures against six domains based on the National Quality Strategy's six priorities, which were developed by the HITPC Workgroups, as follows:

- *Patient and Family Engagement.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and

families in decision making, self care, activation, and understanding of their health condition and its effective management.

• *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

• *Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families in order to improve appropriate and timely patient and care team communication.

• *Population and Public Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served and are especially focused on the leading causes of mortality. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

• *Efficient Use of Healthcare Resources.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

• *Clinical Processes/Effectiveness.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We welcome comments on these domains, and whether they will adequately align with and support the breadth of CMS and HHS activities to improve quality of care and health outcomes.

We also considered the recommendations of the Measure Applications Partnership (MAP) for inclusion of clinical quality measures. The MAP is a public-private partnership convened by the National Quality Forum (NQF) for the primary purpose of providing input to HHS on selecting performance measures for public reporting. The MAP published draft recommendations in their Pre-Rulemaking Report on January 11, 2012 (*http://www.qualityforum.org/map/*), which includes a list of, and rationales for, all the clinical quality measures that the MAP did not support. The MAP did not review the clinical quality measures for 2011 and 2012 that were previously adopted for the EHR Incentive Program in the Stage 1 final rule. We have included some of the clinical quality measures not supported by the MAP in Tables 8 (EPs) and 9 (eligible hospitals and CAHs) to ensure alignment with other CMS quality reporting programs, address recommendations by other Federal advisory committees such as the HITPC, and support other quality goals such as the Million Hearts Campaign. We also included some measures to address specialty areas that may not have had applicable measures in the Stage 1 final rule.

We anticipate that only a subset of these measures will be finalized. When considering which measures to finalize, we will take into account public comment on the measures themselves and the priorities listed previously. We intend to prioritize measures that align with and support the measurement needs of CMS program activities related to quality of care, delivery system reform, and payment reform, especially:

• Encouraging the use of outcome measures, which provide foundational data needed to assess the impact of these programs on population health.

• Measuring progress in preventing and treating priority conditions, including those affecting a large number of CMS beneficiaries or contributing to a large proportion of program costs.

• Improving patient safety and reducing medical harm.

• Capturing the full range of populations served by CMS programs.

4. Measure Specification

We do not intend to use notice and comment rulemaking as a means to update or modify clinical quality measure specifications. A clinical quality measure that has completed the consensus process has a measure steward who has accepted responsibility for maintaining and updating the measure. In general, it is the role of the measure steward to make changes to a measure in terms of the initial patient population, numerator, denominator, and potential exclusions. We recognize that it may be necessary to update measure specifications after they have been published to ensure their continued relevance, accuracy, and validity. Measure specifications updates may include administrative changes, such as adding the NQF endorsement number to a measure, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a measure. These changes would be described in full through supplemental updates to the electronic specifications for EHR submission provided by CMS.

The complete measure specifications would be posted on our Web site (*https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp*) at or around the time of the final rule. In order to assist the public when considering the proposed clinical quality measures in this proposed rule, we would publish tables titled ''Proposed Clinical Quality Measures for 2014 CMS EHR Incentive Programs for Eligible Professionals'' and ''Proposed Clinical Quality Measures for 2014 CMS EHR Incentive Programs for Eligible Hospitals and CAHs'' on this Web site at or around the time of the publication of this proposed rule. These tables contain additional information for the EP, eligible hospital and CAH clinical quality measures, respectively, which may not be found on the NQF Web site. Some of these measures are still being developed, therefore the additional descriptions provided in these tables may still change before the final rule is published. Public comments regarding these measures should be submitted using the same method required for all other comments related to this proposed rule. Please note that the titles and descriptions for the clinical quality measures included in these tables were updated by the measure stewards and therefore may not match the information provided on the NQF Web site. Measures that do not have an NQF number are not currently endorsed.

Measures would be tracked on a version basis as updates to those measures are made. We would require all EPs, eligible hospitals, and CAHs to submit the versions of the clinical quality measure as identified on our Web site, and they would need to include the version numbers when they report the measure. It is our intent to include the version numbers with our updates to the measure specifications.

Under certain circumstances, we believe it may be necessary to remove a clinical quality measure from the EHR Incentive Program between rulemaking cycles. When there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns and/or is no longer scientifically valid, it would be appropriate for us to take immediate action to remove the measure from the EHR Incentive Program and not wait for the rulemaking cycle. Likewise, if a clinical quality measure undergoes a substantive change by the measure steward between rulemaking cycles such that the measure's intent has

changed, we would expect to remove the measure immediately from the EHR Incentive Program until the next rulemaking cycle when we could propose the revised measure for public comment. Under this policy, we would promptly remove such clinical quality measures from the set of measures available for providers to report under the EHR Incentive Program, confirm the removal (or propose the revised measure) in the next EHR Incentive Program rulemaking cycle, and notify providers (EPs, eligible hospitals, and CAHs) and the public of our decision to remove the measure(s) through the usual communication channels (memos, email notification, Web site postings).

5. Proposed Clinical Quality Measures for Eligible Professionals

(a) Statutory and Other Considerations

Sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of clinical quality measures by EPs as part of demonstrating meaningful use of Certified EHR Technology. For further explanation of the statutory requirements, we refer readers to the discussion in our proposed and final rules for Stage 1 (75 FR 1870 through 1902 and 75 FR 44380 through 44435, respectively).

Under sections 1848(o)(1)(D)(iii) and 1903(t)(8) of the Act, the Secretary must seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments for EPs to demonstrate meaningful use of Certified EHR Technology under Medicare and Medicaid. Therefore, to meet this requirement, we continue our practice from Stage 1 of proposing clinical quality measures that would apply for both the Medicare and Medicaid EHR Incentive Programs, as listed in sections II.B.4.(b). and II.B.4.(c). of this proposed rule.

Section 1848(o)(2)(B)(iii) of the Act requires that in selecting measures for EPs, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C) (that is, reporting under the Physician Quality Reporting System). Consistent with that requirement, we are proposing to select clinical quality measures for EPs for the EHR Incentive Programs that align with other existing quality programs such as the Physician Quality Reporting System (PQRS) (76 FR 73026), the Medicare Shared Savings Program (76 FR 67802), measures used by the National Committee for Quality Assurance (NCQA) for medical home accreditation (*http://ncqa.org*), the Health Resources and Services Administration's (HRSA) Uniform Data System (UDS) (75 FR 73170), Children's Health Insurance Program Reauthorization Act (CHIPRA) (75 FR 44314), and the final Section 2701 adult measures under the Affordable Care Act (ACA) published in the **Federal Register** on January 4, 2012 (77 FR 286). When a measure is included in more than one CMS quality reporting program and is reported using Certified EHR Technology, we would seek to avoid requiring EPs to report the same clinical quality measure to separate programs through multiple transactions or mechanisms.

Section 1848(o)(2)(B)(i)(I) of the Act requires the Secretary to give preference to clinical quality measures endorsed by the entity with a contract with the Secretary under section 1890(a) (namely, the National Quality Forum (NQF)). We are proposing clinical quality measures for EPs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference, although we note that the Act does not require the selection of NQF endorsed measures for the EHR Incentive Programs. Measures listed in this proposed rule that do not have an NQF identifying number are not NQF endorsed, but are included in this proposed rule with the intent of eventually obtaining NQF endorsement of those measures determined to be critical to our program.

Per the preamble discussion in the Stage 1 final rule regarding measures gaps and Medicaid providers (75 FR 44506), we are proposing to increase the total number of clinical quality measures for EPs in order to cover areas noted by commenters such as behavioral health, dental care, long-term care, special needs populations, and care coordination. The new measures we are proposing beginning with CY 2014 include new pediatric measures, an obstetric measure, behavioral/mental health measures, and measures related to HIV medical visits and antiretroviral therapy, as well as other measures that address National Quality Strategy goals.

We recognize that we do not have additional measures to propose beginning with CY 2014 in the areas of long-term and post-acute care. Since the publication of the Stage 1 final rule, we have partnered with the National Governor's Association to participate in a panel with long-term care and health information exchange experts to gain insight and consensus on possible clinical quality measures. At this time, however, no clinical quality measures for long-term and post-acute care have been identified as being ready (electronically specified) beginning with CY 2014. We expect to continue to develop or identify clinical quality measures for these areas with our partners and stakeholders for future years.

We are pleased to propose two oral health measures beginning with CY 2014. In the past year, we partnered with Agency for Healthcare Research and Quality (AHRQ) to solicit input from a technical expert panel to identify barriers to the adoption and use of health IT for oral health care providers. A final report titled ''Quality Oral Health Care in Medicaid Through Health IT'' is available at *http://healthit.ahrq.gov/portal/server.pt/community/ahrq-fundedprojects/654/medicaid-schip/14760*. CMS, the American Dental Association, and the Dental Quality Alliance have all strategized ways to encourage and support the use of EHRs for oral health providers. We expect to continue to develop or identify clinical quality measures for dental/oral health care with our partners and stakeholders that could be ready for future years.

(b) Proposed Clinical Quality Measures for Eligible Professionals for CY 2013

We propose that for the EHR reporting periods in CY 2013, EPs must submit data for the clinical quality measures that were finalized in the Stage 1 final rule for CYs 2011 and 2012 (75 FR 44398 through 44411, Tables 6 and 7). Updates to these clinical quality measures' electronic specifications are expected to be posted on the EHR Incentive Program Web site at least 6 months prior to the start of CY 2013 (*https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp*). As required by the Stage 1 final rule, EPs must report on three core or alternate core measures, plus three additional measures. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those clinical quality measures (75 FR 44398 through 44411). The proposed reporting methods for EPs for CY 2013 are discussed in sections II.B.5.(a). and II.B.5.(b). of this proposed rule.

(c) Proposed Clinical Quality Measures for Eligible Professionals Beginning With CY 2014

We are proposing two reporting options that would begin in CY 2014 for Medicare and Medicaid EPs, as described below: Options 1 and 2. For Options 1, we are proposing the following two alternatives, but intend to finalize only a single method:

• Option 1a: EPs would report 12 clinical quality measures from those listed in Table 8, including at least 1 measure from each of the 6 domains.

• Option 1b: EPs would report 11 ''core'' clinical quality measures listed in Table 6 plus 1 ''menu'' clinical quality measure from Table 8.

We welcome comment regarding the advantages and disadvantages of Options 1a and 1b, including EP preference, the appropriateness of the domains, the number of clinical quality measures required, and the appropriate split between ''core'' and ''menu'' clinical quality measures. It is our intent to finalize the most operationally viable and appropriate option or combination of options in our final rule. As an alternative to Options 1a or 1b, Medicare EPs who participate in both the Physician Quality Reporting System and the EHR Incentive Program may choose Option 2, as described below (the Physician Quality Reporting System EHR Reporting Option).

We are proposing clinical quality measures in Table 8 that would apply to all EPs for the EHR reporting periods in CYs 2014 and 2015 (and potentially subsequent years), regardless of whether an EP is in Stage 1 or Stage 2 of meaningful use. For Medicaid EPs, the reporting method for clinical quality measures may vary by State. However, the set of clinical quality measures from which to select (Table 8) would be the same for both Medicaid EPs and Medicare EPs. Medicare EPs who are in their first year of Stage 1 of meaningful use may report clinical quality measures through attestation during the 2 months immediately following the end of the 90-day EHR reporting period as described in section II.B.1. of this proposed rule. Readers should refer to the discussion in the Stage 1 final rule for more information about reporting clinical quality measures through attestation (75 FR 44430 through 44431). We expect that by CY 2016, we will have engaged in another round of rulemaking for the EHR Incentive Programs. However, in the unlikely event such rulemaking does not occur, the clinical quality measures proposed for CYs 2014 and 2015 would continue to apply for the EHR reporting periods in CY 2016 and subsequent years. Therefore, we refer to clinical quality measures that apply ''beginning with'' or ''beginning in'' CY 2014.

• Option 1a: Select and submit 12 clinical quality measures from Table 8, including at least 1 measure from each of the 6 domains.

We are proposing that EPs must report 12 clinical quality measures from those listed in Table 8, which must include at least one measure from each of the following 6 domains, which are described in section II.B.3. of this proposed rule:

• Patient and Family Engagement.
• Patient Safety.
• Care Coordination.
• Population and Public Health.
• Efficient Use of Healthcare Resources.
• Clinical Process/Effectiveness.

EPs would select the clinical quality measures that best apply to their scope of practice and/or unique patient population. If an EP's Certified EHR Technology does not contain patient data for at least 12 clinical quality measures, then the EP must report the clinical quality measures for which there is patient data and report the remaining required clinical quality measures as ''zero denominators'' as displayed by the EPs Certified EHR Technology. If there are no clinical quality measures applicable to the EP's scope of practice or unique patient populations, EPs must still report 12 clinical quality measures even if zero is the result in either the numerator and/or the denominator of the measure. If all applicable clinical quality measures have a value of zero from their Certified EHR Technology, then EPs must report any 12 of the clinical quality measures. For this option, the clinical quality measures data would be submitted in an XML-based format on an aggregate basis reflective of all patients without regard to payer. One advantage of this approach is that EPs can choose measures that best fit their practice and patient populations. However, because of the large number of measures to choose from, this approach would result in fewer EPs reporting on any given measure, and likely only a small sample of patient data represented in each measure.

• Option 1b: Submit 12 clinical quality measures composed of all 11 of the core clinical quality measures in Table 6 plus 1 menu clinical quality measure from Table 8.

We are considering a ''core'' clinical quality measure set that all EPs must report, which will reflect the national priorities outlined in section II.B.3. of this proposed rule. In addition to the core clinical quality measure set, we are considering a ''menu'' set from which EPs would select 1 clinical quality measure to report based on their respective scope of practice and/or unique patient population. One advantage of this approach is that quality data would be collected on a smaller set of measures, so the resulting data for each measure would represent a larger number of patients and therefore could be more accurate. However, this approach could mean that more measures are reported with zero denominators (if they are not applicable to certain practices or populations), making the data less comprehensive. The menu set would consist of the measures in Table 8 that are not part of the core clinical quality measure set. The core clinical quality measure set for EPs consists of the following measures in Table 6 (these clinical quality measures are also in Table 8):

TABLE 6—POTENTIAL CORE CLINICAL QUALITY MEASURE SET TO BE REPORTED BY ELIGIBLE PROFESSIONALS BEGINNING IN CY 2014

Measure Number	Clinical quality measure title & description	Clinical quality measure steward & contact information	Domain
TBD	Title: Closing the referral loop: receipt of specialist report Description: Percentage of patients regardless of age with a referral from a primary care provider for whom a report from the provider to whom the patient was referred was received by the referring provider.	Centers for Medicare and Medicaid Services (CMS). 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;* Quality Insights of Pennsylvania (QIP) Contact Information: *www.usqualitymeasures.org*.	Care Coordination.

TABLE 6—POTENTIAL CORE CLINICAL QUALITY MEASURE SET TO BE REPORTED BY ELIGIBLE PROFESSIONALS BEGINNING IN CY 2014—Continued

Measure Number	Clinical quality measure title & description	Clinical quality measure steward & contact information	Domain
TBD	Title: Functional status assessment for complex chronic conditions; Description: Percentage of patients aged 65 years and older with heart failure and two or more high impact conditions who completed initial and follow-up (patient-reported) functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.	Patient and Family Engagement.
NQF 0018	Title: Controlling High Blood Pressure; Description: Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled during the measurement year.	NCQA Contact Information: *www.ncqa.org*.	Clinical Process/ Effectiveness.
NQF 0097	Title: Medication Reconciliation; Description: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* National Committee for Quality Assurance (NCQA) Contact information: *www.ncqa.org*.	Patient Safety.
NQF 0418	Title: Screening for Clinical Depression; Description: Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool and follow up plan documented.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.	Population/Public Health.
NQF 0028	Title: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention; Description: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI Contact Information: *cpe@ama-assn.org*.	Population/Public Health.
TBD	Title: Preventive Care and Screening: Cholesterol—Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL; Description: Percentage of patients aged 20 through 79 years whose risk factors * have been assessed and a fasting LDL test has been performed. Percentage of patients aged 20 through 79 years who had a fasting LDL test performed and whose risk-stratified* fasting LDL is at or below the recommended LDL goal.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;* QIP Contact Information: *www.usqualitymeasures.org*.	Clinical Process/ Effectiveness.
NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic; Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year.	NCQA Contact Information: *www.ncqa.org*.	Clinical Process/ Effectiveness.
NQF 0024	Title: Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents; Description: Percentage of patients 3–17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or OB/GYN and who had evidence of body mass index (BMI) percentile documentation, counseling for nutrition and counseling for physical activity during the measurement year.	NCQA Contact information: *www.ncqa.org*.	Population/Public Health.
NQF 0022	Title: Use of High-Risk Medications in the Elderly; Description: Percentage of patients ages 65 years and older who received at least one high-risk medication. Percentage of patients 65 years of age and older who received at least two different high-risk medications.	NCQA Contact Information: *www.ncqa.org*.	Patient Safety.
TBD	Title: Adverse Drug Event (ADE) Prevention: Outpatient therapeutic drug monitoring; Description: Percentage of patients 18 years of age and older receiving outpatient chronic medication therapy who had the appropriate therapeutic drug monitoring during the measurement year.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.	Patient Safety.

We selected these measures for the proposed core set based upon analysis of several factors that include: conditions that contribute the most to Medicare and Medicaid beneficiaries' morbidity and mortality; conditions that represent national public/population health priorities; conditions that are common to health disparities; those conditions that disproportionately drive healthcare costs that could improve with better quality measurement; measures that would enable CMS, States, and the provider community to measure quality of care in new dimensions with a stronger focus on parsimonious measurement; and those measures that include patient and/or caregiver engagement.

We request public comment on the core and menu set reporting schema

described as well as the number and appropriateness of the core set listed in Table 6. We are considering that all identified core clinical quality measures must be reported by all EPs in addition to a menu set clinical quality measure. The policy on reporting ''zeros'' discussed previously under Option 1a would also apply for this core and menu option. In this option, an EP who does not report all of the identified core clinical quality measures, plus a menu set clinical quality measure, would have not met the requirements for submitting the clinical quality measures.

• Option 2: Submit and satisfactorily report clinical quality measures under the Physician Quality Reporting System's EHR Reporting Option.

We propose an alternative option for Medicare EPs who participate in both the Physician Quality Reporting System and the EHR Incentive Program. As an alternative to reporting the 12 clinical quality measures as described under Options 1a and 1b, and in order to streamline quality reporting options for participating providers, Medicare EPs who submit and satisfactorily report Physician Quality Reporting System clinical quality measures under the Physician Quality Reporting System's EHR reporting option using Certified EHR Technology would satisfy their clinical quality measures reporting requirement under the Medicare EHR Incentive Program. For more information about the requirements of the Physician Quality Reporting System, we refer readers to 42 CFR 414.90 and the CY 2012 Medicare Physician Fee Schedule final rule with comment period (76 FR 73314). EPs who choose this option to satisfy their clinical quality measures reporting obligation under the Medicare EHR Incentive Program would be required to comply with any changes to the requirements of the Physician Quality Reporting System that may apply in future years.

Table 7 lists the clinical quality measures that were finalized in the Stage 1 final rule (75 FR 44398 through 44408) that we are proposing to eliminate beginning with CY 2014.

TABLE 7—CLINICAL QUALITY MEASURES INCLUDED IN THE STAGE 1 FINAL RULE THAT ARE PROPOSED TO BE ELIMINATED BEGINNING IN CY 2014

Measure No.	Clinical quality measure title & description	Clinical quality measure developer* & contact information
NQF# 0013	Title: Hypertension: Blood Pressure Management; Description: Percentage of patient visits aged 18 years and older with a diagnosis of hypertension who have been seen for at least 2 office visits, with blood pressure (BP) recorded.	AMA–PCPI Contact Information: *cpe@ama-assn.org*.
NQF# 0027	Title: Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Strategies.	NCQA Contact Information: *www.ncqa.org*.
NQF# 0084	Title: Heart Failure (HF): Warfarin Therapy Patients with Atrial Fibrillation; Description: Percentage of all patients aged 18 years and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.	AMA–PCPI Contact Information: *cpe@ama-assn.org*.

*AMA–PCPI = American Medical Association-Physician Consortium for Performance Improvement.
NCQA = National Committee for Quality Assurance.

Based in part on the feedback received throughout Stage 1, we propose to eliminate these three clinical quality measures beginning with CY 2014 for EPs at all Stages for the following reasons:

• NQF # 0013—The measure steward did not submit this measure to the National Quality Forum for continued endorsement. We have included other measures that address high blood pressure and hypertension in Table 8.

• NQF #0027—We determined this measure is very similar to NQF #0028 a and b; therefore, to avoid duplication of measures, we propose to only retain NQF # 0028 a and b.

• NQF #0084—The measure steward did not submit this measure to the National Quality Forum for continued endorsement. Additionally, CMS has decided to remove this measure because there are other FDA-approved anticoagulant therapies available in addition to Warfarin. We are proposing to replace this measure, pending availability of electronic specifications, with NQF #1525—Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Table 8 lists all of the clinical quality measures that we are considering for EPs to report for the EHR Incentive Programs beginning with CY 2014. However, we expect to finalize only a subset of these proposed measures based on public comment and the priorities listed in section II.B.3. of this proposed rule. The measures titles and descriptions in Table 8 reflect the most current updates, as provided by the measure stewards who are responsible for maintaining and updating the measure specifications,; and therefore, may not reflect the title and/or description as presented on the NQF Web site. Measures which are designated as ''New'' in the ''New Measures'' column were not finalized in the Stage 1 final rule. Please note that measures which are listed as also being part of the ''ACO'' program in the ''Other Quality Programs that Use the Same Measure'' column of Table 8 are Medicare Shared Savings Program measures. Some of the clinical quality measures in Table 8 will require the development of electronic specifications. Therefore, we propose to consider these measures for inclusion beginning with CY 2014 based on our expectation that their electronic specifications will be available at the time of or within a reasonable period after the publication of the final rule.

Additionally, some of these measures have not yet been submitted for consensus endorsement consideration or are currently under review for endorsement consideration by the National Quality Forum. We expect that any measure proposed in Table 8 for inclusion beginning with CY 2014 will be submitted for endorsement consideration by the measure steward. The finalized list of measures that would apply for EPs beginning with CY 2014 will be published in the final rule. Because measure specifications may need to be updated more frequently than our expected rulemaking cycle would allow for, we would provide updates to the specifications at least 6 months prior to the beginning of the calendar year for which the measures would be required, and we expect to update specifications annually. All clinical quality measure specification updates, including a schedule for updates to electronic specifications,

would be posted on the EHR Incentive Program Web site (*https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp*), and we would notify the public of the posting.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 0001	Title: Asthma: Assessment of Asthma Control Description: Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated at least once for asthma control (comprising asthma impairment and asthma risk).	American Medical Association-Physician Consortium for Performance Improvement (AMA–PCPI). Contact Information: *cpe@ama-assn.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0002	Title: Appropriate Testing for Children with Pharyngitis Description: Percentage of children 2–18 years of age who were diagnosed with pharyngitis, dispensed an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance (NCQA). Contact Information: *www.ncqa.org.*	EHR PQRS, CHIPRA		Efficient Use of Healthcare Resources.
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement. Description: The percentage of adolescent and adult patients with a new episode of alcohol and other drug (AOD) dependence who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis and who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, HEDIS, State use, ACA 2701, NCQA–PCMH Accreditation.		Clinical Process/Effectiveness.
NQF 0012	Title: Prenatal Care: Screening for Human Immunodeficiency Virus (HIV). Description: Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal care visit.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS		Population/Public Health.
NQF 0014	Title: Prenatal Care: Anti-D Immune Globulin Description: Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26–30 weeks gestation.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS, NCQA–PCMH Accreditation.		Patient Safety.
NQF 0018	Title: Controlling High Blood Pressure Description: Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled during the measurement year.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Clinical Process/Effectiveness.
NQF 0022	Title: Use of High-Risk Medications in the Elderly Description: Percentage of patients ages 65 years and older who received at least one high-risk medication. Percentage of patients 65 years of age and older who received at least two different high-risk medications.	NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient Safety.
NQF 0024	Title: Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents. Description: Percentage of patients 3–17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or OB/GYN and who had evidence of body mass index (BMI) percentile documentation, counseling for nutrition and counseling for physical activity during the measurement year.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, UDS		Population/Public Health.
NQF 0028	Title: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. Description: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Population/Public Health.
NQF 0031	Title: Breast Cancer Screening Description: Percentage of women 40–69 years of age who had a mammogram to screen for breast cancer.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, ACA 2701, HEDIS, State use, NCQA–PCMH Accreditation.		Clinical Process/Effectiveness.
NQF 0032	Title: Cervical Cancer Screening Description: Percentage of women 21–64 years of age, who received one or more Pap tests to screen for cervical cancer.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, ACA 2701, HEDIS, State use, NCQA–PCMH Accreditation, UDS.		Clinical Process/Effectiveness.
NQF 0033	Title: Chlamydia Screening in Women Description: Percentage of women 16–24 years of age who were identified as sexually active and who had at least one test for Chlamydia during the measurement year.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, CHIPRA, ACA 2701, HEDIS, State use, NCQA–PCMH Accreditation.		Population/Public Health.
NQF 0034	Title: Colorectal Cancer Screening Description: Percentage of adults 50–75 years of age who had appropriate screening for colorectal cancer.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, NCQA–PCMH Accreditation.		Clinical Process/Effectiveness.
NQF 0036	Title: Use of Appropriate Medications for Asthma Description: Percentage of patients 5–50 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year. Report three age stratifications (5–11 years, 12–50 years, and total).	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0038	Title: Childhood Immunization Status Description: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); two H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. The measure calculates a rate for each vaccine and nine separate combination rates.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, UDS		Population/Public Health.
NQF 0041	Title: Preventative Care and Screening: Influenza Immunization Description: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS, ACO, Group Reporting PQRS.		Population/Public Health.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 0043	Title: Pneumonia Vaccination Status for Older Adults Description: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, NCQA–PCMH Accreditation.		Clinical Process/Effectiveness.
NQF 0045	Title: Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture. Description: Percentage of patients aged 50 years and older treated for a hip, spine, or distal radial fracture with documentation of communication with the physician managing the patient's ongoing care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis.	NCQA Contact Information: *www.ncqa.org.*	PQRS, NCQA–PCMH Accreditation.	New	Care Coordination.
NQF 0046	Title: Osteoporosis: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older. Description: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	NCQA Contact Information: *www.ncqa.org.*	PQRS, NCQA–PCMH Accreditation.	New	Clinical Process/Effectiveness.
NQF 0047	Title: Asthma Pharmacologic Therapy for Persistent Asthma Description: Percentage of patients aged 5 through 50 years with a diagnosis of persistent asthma and at least one medical encounter for asthma during the measurement year who were prescribed long-term control medication.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS, UDS		Clinical Process/Effectiveness.
NQF 0048	Title: Osteoporosis: Management Following Fracture of Hip, Spine or Distal radius for Men and Women Aged 50 Years and Older. Description: Percentage of patients aged 50 years or older with fracture of the hip, spine or distal radius that had a central dual-energy X-ray absorptiometry measurement ordered or performed or pharmacologic therapy prescribed.	NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0050	Title: Osteoarthritis (OA): Function and Pain Assessment Description: Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with assessment for function and pain.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
NQF 0051	Title: Osteoarthritis (OA): assessment for use of anti-inflammatory or analgesic over-the-counter (OTC) medications. Description: Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with an assessment for use of anti-inflammatory or analgesic OTC medications.	AMA–PCPI Contact Information: *cpe@ama-assn.org*	PQRS	New	Clinical Process/Effectiveness.
NQF 0052	Title: Use of Imaging Studies for Low Back Pain Description: Percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain x-ray, MRI, CT scan) within 28 days of diagnosis.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS		Efficient Use of Healthcare Resources.
NQF 0055	Title: Diabetes: Eye Exam Description: Percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had a retinal or dilated eye exam or a negative retinal exam (no evidence of retinopathy) by an eye care professional.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0056	Title: Diabetes: Foot Exam Description: The percentage of patients aged 18–75 years with diabetes (type 1 or type 2) who had a foot exam (visual inspection, sensory exam with monofilament, or pulse exam).	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0058	Title: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis. Description: Percentage of adults ages 18 through 64 years with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription on or within 3 days of the initial date of service.	NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Efficient Use of Healthcare Resources.
NQF 0059	Title: Diabetes: Hemoglobin A1c Poor Control Description: Percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c >9.0%.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Clinical Process/Effectiveness.
NQF 0060	Title: Hemoglobin A1c Test for Pediatric Patients Description: Percentage of pediatric patients with diabetes with an HbA1c test in a 12-month measurement period.	NCQA Contact Information: *www.ncqa.org.*		New	Clinical Process/Effectiveness.
NQF 0061	Title: Diabetes: Blood Pressure Management Description: Percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had blood pressure <140/90 mmHg.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0062	Title: Diabetes: Urine Screening Description: Percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy.	NCQA Contact Information: *www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0064	Title: Diabetes: Low Density Lipoprotein (LDL) Management and Control. Description: Percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had LDL–C <100 mg/dL.	NCQA Contact Information: *www.ncqa.org.*	PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0066	Title: Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%). Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) <40% who were prescribed ACE inhibitor or ARB therapy.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	ACO, Group Reporting PQRS.	New	Clinical Process/Effectiveness.
NQF 0067	Title: Coronary Artery Disease (CAD): Antiplatelet Therapy Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic. Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year.	NCQA ..... Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS.	.....	Clinical Process/Effectiveness.
NQF 0069	Title: Appropriate Treatment for Children with Upper Respiratory Infection (URI). Description: Percentage of children who were given a diagnosis of URI and were not dispensed an antibiotic prescription on or three days after the episode date.	NCQA ..... Contact Information: *www.ncqa.org.*	PQRS, NCQA–PCMH Accreditation.	New	Efficient Use of Healthcare Resources.
NQF 0070	Title: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%). Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI or a current or prior LVEF <40% who were prescribed beta-blocker therapy.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	EHR PQRS, NCQA–PCMH Accreditation.	.....	Clinical Process/Effectiveness.
NQF 0073	Title: Ischemic Vascular Disease (IVD): Blood Pressure Management. Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and whose recent blood pressure is in control (<140/90 mmHg).	NCQA ..... Contact Information: *www.ncqa.org.*	EHR PQRS	.....	Clinical Process/Effectiveness.
NQF 0074	Title: Coronary Artery Disease (CAD): Lipid Control ..... Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL–C result <100mg/dL OR patients who have a LDL–C result ≥100mg/dL and have a documented plan of care to achieve LDL–C <100mg/dL, including at a minimum the prescription of a statin.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	PQRS, ACO, Group Reporting PQRS.	.....	Clinical Process/Effectiveness.
NQF 0075	Title: Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control. Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal angioplasty (PTCA) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had a complete lipid profile performed during the measurement year and whose LDL–C<100 mg/dL.	NCQA ..... Contact Information: *www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS.	.....	Clinical Process/Effectiveness.
NQF 0081	Title: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD). Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	EHR PQRS, Group Reporting PQRS, NCQA–PCMH Accreditation.	.....	Clinical Process/Effectiveness.
NQF 0083	Title: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD). Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	EHR PQRS, ACO, Group Reporting PQRS.	.....	Clinical Process/Effectiveness.
NQF 0086	Title: Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation. Description: Percentage of patients aged 18 years and older with a diagnosis of POAG who have an optic nerve head evaluation during one or more office visits within 12 months.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	EHR PQRS	.....	Clinical Process/Effectiveness.
NQF 0088	Title: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy. Description: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	EHR PQRS	.....	Clinical Process/Effectiveness.
NQF 0089	Title: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care. Description: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	EHR PQRS	.....	Clinical Process/Effectiveness.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 0097	Title: Medication Reconciliation ..... Description: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	ACO, Group Reporting PQRS, NCQA–PCMH Accreditation.	New	Patient Safety.
NQF 0098	Title: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Age 65 Years and Older. Description: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	NCQA ..... Contact Information: *www.ncqa.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0100	Title: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older. Description: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient and Family Engagement.
NQF 0101	Title: Falls: Screening for Falls Risk ..... Description: Percentage of patients aged 65 years and older who were screened for future fall risk (patients are considered at risk for future falls if they have had 2 or more falls in the past year or any fall with injury in the past year) at least once within 12 months.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS, ACO, Group Reporting PQRS.	New	Patient Safety.
NQF 0102	Title: Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy. Description: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	PQRS, Group Reporting PQRS.	New	Clinical Process/Effectiveness.
NQF 0103	Title: Major Depressive Disorder (MDD): Diagnostic Evaluation ..... Description: Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who met the DSM–IV criteria during the visit in which the new diagnosis or recurrent episode was identified during the measurement period.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0104	Title: Major Depressive Disorder (MDD): Suicide Risk Assessment .. Description: Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who had a suicide risk assessment completed at each visit during the measurement period.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0105	Title: Anti-depressant Medication Management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment. Description: The percentage of patients 18 years of age and older who were diagnosed with a new episode of major depression, treated with antidepressant medication, and who remained on an antidepressant medication treatment.	NCQA ..... Contact Information: *www.ncqa.org.*	EHR PQRS, HEDIS, State use, ACA 2701.	.....	Clinical Process/Effectiveness.
NQF 0106	Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents. Description: Percentage of patients newly diagnosed with ADHD whose medical record contains documentation of DSM–IV–TR or DSM–PC criteria.	Institute for Clinical Systems Improvement (ICSI). Contact Information: *www.icsi.org*	.....	New	Care Coordination.
NQF 0107	Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents. Description: Percentage of patients treated with psychostimulant medication for the diagnosis of ADHD whose medical record contains documentation of a follow-up visit at least twice a year.	ICSI ..... Contact Information: *www.icsi.org*	.....	New	Clinical Process/Effectiveness.
NQF 0108	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication. Description: (a) Initiation Phase: Percentage of children 6–12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Continuation and Maintenance (C&M) Phase: Percentage of children 6–12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication who remained on the medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	NCQA ..... Contact Information: *www.ncqa.org.*	.....	New	Clinical Process/Effectiveness.
NQF 0110	Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use. Description: Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health (CQAIMH). Contact Information: *www.cqaimh.org; cqaimh@cqaimh.org.*	NCQA–PCMH Accreditation.	New	Clinical Process/Effectiveness.
NQF 0112	Title: Bipolar Disorder: Monitoring change in level-of-functioning ..... Description: Percentage of patients aged 18 years and older with an initial diagnosis or new episode/presentation of bipolar disorder.	CQAIMH ..... Contact Information: *www.cqaimh.org; cqaimh@cqaimh.org.*	.....	New	Clinical Process/Effectiveness.
NQF 0239	Title: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (when indicated in ALL patients). Description: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	AMA–PCPI ..... Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient Safety.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
Formerly NQF 0246, no longer endorsed.	Title: Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports. Description: Percentage of final reports for CT or MRI studies of the brain performed either: • In the hospital within 24 hours of arrival, OR • In an outpatient imaging center to confirm initial diagnosis of stroke, transient ischemic attack (TIA) or intracranial hemorrhage.. For patients aged 18 years and older with either a diagnosis of ischemic stroke, TIA or intracranial hemorrhage OR at least one documented symptom consistent with ischemic stroke, TIA or intracranial hemorrhage that includes documentation of the presence or absence of each of the following: hemorrhage, mass lesion and acute infarction.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0271	Title: Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures). Description: Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS, NCQA–PCMH Accreditation.	New	Patient Safety.
NQF 0312	Title: Lower Back Pain: Repeat Imaging Studies Description: Percentage of patients with back pain who received inappropriate imaging studies in the absence of red flags or progressive symptoms (overuse measure, lower performance is better).	NCQA Contact Information: *www.ncqa.org.*		New	Efficient Use of Healthcare Resources.
NQF 0321	Title: Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute Description: Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a Kt/V≤ = 1.7 per week measured once every 4 months.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Care Coordination.
NQF 0322	Title: Back Pain: Initial Visit Description: The percentage of patients with a diagnosis of back pain who have medical record documentation of all of the following on the date of the initial visit to the physician: 1. Pain assessment 2. Functional status 3. Patient history, including notation of presence or absence of "red flags". 4. Assessment of prior treatment and response, and 5. Employment status	NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Efficient Use of Healthcare Resources.
NQF 0323	Title: Adult Kidney Disease: Hemodialysis Adequacy: Solute Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) receiving hemodialysis three times a week have a spKt/V≥1.2.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Care Coordination.
NQF 0382	Title: Oncology: Radiation Dose Limits to Normal Tissues Description: Percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	AMA–PCPI Contact Information: *cpe@ama-assn.org;.*	PQRS	New	Patient Safety.
NQF 0383	Title: Oncology: Measure Pair: Oncology: Medical and Radiation—Plan of Care for Pain. Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
NQF 0384	Title: Oncology: Measure Pair: Oncology: Medical and Radiation–Pain Intensity Quantified. Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
NQF 0385	Title: Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients. Description: Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.	AMA–PCPI Contact Information: *cpe@ama-assn.org; American Society of Clinical Oncology (ASCO): www.asco.org; National Comprehensive Cancer Network (NCCN): www.nccn.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0387	Title: Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer. Description: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA–PCPI Contact Information: *cpe@ama-assn.org; ASCO: www.asco.org; NCCN: www.nccn.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0388	Title: Prostate Cancer: Three Dimensional (3D) Radiotherapy Description: Percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving external beam radiotherapy as a primary therapy to the prostate with or without nodal irradiation (no metastases; no salvage therapy) who receive three-dimensional conformal radiotherapy (3D–CRT) or intensity modulated radiation therapy (IMRT).	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient Safety.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 0389	Title: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients. Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did *not* have a bone scan performed at any time since diagnosis of prostate cancer.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	EHR PQRS		Efficient Use of Healthcare Resources.
NQF 0399	Title: Hepatitis C: Hepatitis A Vaccination in Patients with HCV Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS, NCQA–PCMH Accreditation.	New	Population/Public Health.
NQF 0400	Title: Hepatitis C: Hepatitis B Vaccination in Patients with HCV Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS, NCQA–PCMH Accreditation.	New	Population/Public Health.
NQF 0401	Title: Hepatitis C: Counseling Regarding Risk of Alcohol Consumption. Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12 months.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS, NCQA–PCMH Accreditation.	New	Clinical Process/Effectiveness.
NQF 0403	Title: Medical Visits Description: Percentage of patients regardless of age, with a diagnosis of HIV/AIDS with at least one medical visit in each 6 month period with a minimum of 60 days between each visit.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*		New	Clinical Process/Effectiveness.
NQF 0405	Title: Pneumocystitis jiroveci pneumonia (PCP) Prophylaxis Description: Percentage of patients with HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS, NCQA–PCMH Accreditation.	New	Clinical Process/Effectiveness.
NQF 0406	Title: Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy. Description: Percentage of patients who were prescribed potent antiretroviral therapy.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS, NCQA–PCMH Accreditation.	New	Clinical Process/Effectiveness.
NQF 0407	Title: HIV RNA control after six months of potent antiretroviral therapy. Description: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who had at least two medical visits during the measurement year, with at least 60 days between each visit, who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy OR whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and has a documented plan of care.	NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0418	Title: Screening for Clinical Depression Description: Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool and follow up plan documented.	Centers for Medicare and Medicaid Services (CMS). 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;*. Quality Insights of Pennsylvania (QIP). Contact Information: *www.usqualitymeasures.org.*	EHR PQRS, ACO	New	Population/Public Health.
NQF 0419	Title: Documentation of Current Medications in the Medical Record Description: Percentage of specified visits as defined by the denominator criteria for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list must include ALL prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route.	Centers for Medicare and Medicaid Services (CMS) 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;* QIP. Contact Information: *www.usqualitymeasures.org.*	PQRS, EHR PQRS, Group Reporting PQRS.	New	Patient Safety.
NQF 0421	Title: Adult Weight Screening and Follow-Up Description: Percentage of patients aged 18 years and older with a calculated body mass index (BMI) in the past six months or during the current visit documented in the medical record AND if the most recent BMI is *outside* of normal parameters, a follow-up plan is documented. Normal Parameters: Age 65 years and older BMI ≥23 and <30 Age 18–64 years BMI ≥18/5 and <25	Centers for Medicare and Medicaid Services (CMS) 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;*. QIP Contact Information: *www.usqualitymeasures.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Population/Public Health.
NQF 0507	Title: Radiology: Stenosis Measurement in Carotid Imaging Studies Description: Percentage of final reports for all patients, regardless of age, for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computer tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0508	Title: Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening. Description: Percentage of final reports for screening mammograms that are classified as "probably benign."	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Efficient Use of Healthcare Resources.
NQF 0510	Title: Radiology: Exposure Time Reported for Procedures Using Fluoroscopy. Description: Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient Safety.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 0513	Title: Thorax CT: Use of Contrast Material Description: This measure calculates the percentage of thorax studies that are performed with and without contrast out of all thorax studies performed (those with contrast, those without contrast, and those with both).	CMS Contact Information: 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Efficient Use of Healthcare Resources.
NQF 0519	Title: Diabetic Foot Care and Patient/Caregiver Education Implemented During Short Term Episodes of Care. Description: Percentage of short term home health episodes of care during which diabetic foot care and education were included in the physician-ordered plan of care and implemented for patients with diabetes.	CMS Contact Information: 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Care Coordination.
NQF 0561	Title: Melanoma: Coordination of Care Description: Percentage of patient visits, regardless of patient age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physicians(s) providing continuing care within one month of diagnosis.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org*.	PQRS	New	Care Coordination.
NQF 0562	Title: Melanoma: Overutilization of Imaging Studies in Melanoma Description: Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	AMA–PCPI Contact Information: *cpe@ama-assn.org; NCQA* Contact Information: *www.ncqa.org*.	PQRS	New	Efficient Use of Healthcare Resources.
NQF 0564	Title: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures. Description: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org*.	PQRS	New	Patient Safety.
NQF 0565	Title: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery. Description: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org*.	PQRS	New	Clinical Process/Effectiveness.
NQF 0575	Title: Diabetes: Hemoglobin A1c Control (<8.0%) Description: The percentage of patients 18–75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c <8.0%.	NCQA Contact Information: *www.ncqa.org*.	EHR PQRS, Group Reporting PQRS, UDS.		Clinical Process/Effectiveness.
NQF 0608	Title: Pregnant women that had HBsAg testing Description: This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.	Ingenix Contact Information: *www.ingenix.com*.		New	Clinical Process/Effectiveness.
NQF 0710	Title: Depression Remission at Twelve Months Description: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ–9 score >9 who demonstrate remission at twelve months defined as PHQ–9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ–9 score indicates a need for treatment.	Minnesota Community Measurement (MNCM). Contact Information: *www.mncm.org; info@mncm.org*.		New	Clinical Process/Effectiveness.
NQF 0711	Title: Depression Remission at Six Months Description: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ–9 score >9 who demonstrate remission at six months defined as PHQ–9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ–9 score indicates a need for treatment.	MNCM Contact Information: *www.mncm.org; info@mncm.org*.		New	Clinical Process/Effectiveness.
NQF 0712	Title: Depression Utilization of the PHQ–9 Tool Description: Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ–9 tool administered at least once during a 4 month period in which there was a qualifying visit.	MNCM Contact Information: *www.mncm.org; info@mncm.org*.		New	Clinical Process/Effectiveness.
NQF 1335	Title: Children who have dental decay or cavities Description: Assesses if children aged 1–17 years have had tooth decay or cavities in the past 6 months.	Maternal and Child Health Bureau, Health Resources and Services Adminstration *http://mchb.hrsa.gov/*.		New	Clinical Process/Effectiveness.
NQF 1365	Title: Child and Adolescent Major Depressive Disorder: Suicide Risk Assessment. Description: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	AMA–PCPI Contact Information: *cpe@ama-assn.org*.		New	Patient Safety.
NQF 1401	Title: Maternal depression screening Description: The percentage of children who turned 6 months of age during the measurement year who had documentation of a maternal depression screening for the mother.	NCQA Contact Information: *www.ncqa.org*.		New	Population/Public Health.
NQF 1419	Title: Primary Caries Prevention Intervention as Part of Well/Ill Child Care as Offered by Primary Care Medical Providers. Description: The measure will a) track the extent to which the PCMP or clinic (determined by the provider number used for billing) applies FV as part of the EPSDT examination and b) track the degree to which each billing entity's use of the EPSDT with FV codes increases from year to year (more children varnished and more children receiving FV four times a year according to ADA recommendations for high-risk children).	University of Minnesota Contact Information: *www.umn.edu* ...		New	Clinical Process/Effectiveness.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
NQF 1525	Title: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy. Description: Percentage of patients aged 18 years and older with nonvalvular AF or atrial flutter at high risk for thromboembolism, according to CHADS2 risk stratification, who were prescribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism during the 12-month reporting period.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* American College of Cardiology Foundation (ACCF) *www.cardiosource.org;* American Heart Association (AHA) *www.heart.org.*		New	Clinical Process/Effectiveness.
TBD	Title: Preventive Care and Screening: Cholesterol—Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL. Description: Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed. Percentage of patients aged 20 through 79 years who had a fasting LDL test performed and whose risk-stratified* fasting LDL is at or below the recommended LDL goal.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;* QIP Contact Information: *www.usqualitymeasures.org.*	EHR PQRS	New	Clinical Process/Effectiveness.
TBD	Title: Falls: Risk Assessment for Falls Description: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient Safety.
TBD	Title: Falls: Plan of Care for Falls Description: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient Safety.
TBD	Title: Adult Kidney Disease: Blood Pressure Management Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5 not receiving RRT) and proteinuria with a blood pressure <130/80 mmHg or ≥130/80 mmHg with documented plan of care.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*		New	Clinical Process/Effectiveness.
TBD	Title: Adult Kidney Disease: Patients on Erythropoiesis Stimulating Agent (ESA)-Hemoglobin Level >12.0 g/dL. Description: Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) level is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or end-stage renal disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy have a hemoglobin (Hgb) level >12.0 g/dL.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*		New	Efficient Use of Healthcare Resources.
TBD	Title: Chronic Wound Care: Use of wet to dry dressings in patients with chronic skin ulcers (overuse measure). Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer *without* a prescription or recommendation to use wet to dry dressings.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient Safety.
TBD	Title: Dementia: Staging of Dementia Description: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate, or severe at least once within a 12 month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Clinical Process/Effectiveness.
TBD	Title: Dementia: Cognitive Assessment Description: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Clinical Process/Effectiveness.
TBD	Title: Dementia: Functional Status Assessment Description: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
TBD	Title: Dementia: Counseling Regarding Safety Concerns Description: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
TBD	Title: Dementia: Counseling Regarding Risks of Driving Description: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient Safety.
TBD	Title: Dementia: Caregiver Education and Support Description: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional resources for support within a 12-month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
TBD	Title: Chronic Wound Care: Patient education regarding long term compression therapy. Description: Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy including interval replacement of compression stockings within the 12 month reporting period.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*		New	Patient and Family Engagement.
TBD	Title: Rheumatoid Arthritis (RA): Functional Status Assessment Description: Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient and Family Engagement.
TBD	Title: Glaucoma Screening in Older Adults Description: Percentage of patients 65 years and older, without a prior diagnosis of glaucoma or glaucoma suspect, who received a glaucoma eye exam by an eye-care professional for early identification of glaucomatous conditions.	NCQA Contact Information: *www.ncqa.org.*		New	Clinical Process/Effectiveness.

TABLE 8—CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014—Continued

Measure No.	Clinical quality measure title & description	Clinical quality measure steward & contact information	Other quality measure programs that use the same measure**	New measure	Domain
TBD	Title: Chronic Wound Care: Patient Education regarding diabetic foot care. Description: Percentage of patients aged 18 years and older with a diagnosis of diabetes and foot ulcer who received education regarding appropriate foot care AND daily inspection of the feet within the 12 month reporting period.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*		New	Patient and Family Engagement.
TBD	Title: Hypertension: Improvement in blood pressure Description: Percentage of patients aged 18 years and older with hypertension whose blood pressure improved during the measurement period.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139.*		New	Clinical Process/Effectiveness.
TBD	Title: Closing the referral loop: receipt of specialist report Description: Percentage of patients regardless of age with a referral from a primary care provider for whom a report from the provider to whom the patient was referred was received by the referring provider.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139.*		New	Care Coordination.
TBD	Title: Functional status assessment for knee replacement Description: Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139.*		New	Patient and Family Engagement.
TBD	Title: Functional status assessment for hip replacement Description: Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139.*		New	Patient and Family Engagement.
TBD	Title: Functional status assessment for complex chronic conditions Description: Percentage of patients aged 65 years and older with heart failure and two or more high impact conditions who completed initial and follow-up (patient-reported) functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139.*		New	Patient and Family Engagement.
TBD	Title: Adverse Drug Event (ADE) Prevention: Outpatient therapeutic drug monitoring. Description: Percentage of patients 18 years of age and older receiving outpatient chronic medication therapy who had the appropriate therapeutic drug monitoring during the measurement year.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139.*		New	Patient Safety.
TBD	Title: Preventive Care and Screening: Screening for High Blood Pressure. Description: Percentage of patients aged 18 years and older who are screened for high blood pressure.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;.* QIP Contact Information: *www.usqualitymeasures.org.*	PQRS, Group Reporting PQRS, ACO.	New	Population/Public Health.
TBD	Title: Hypertension: Blood Pressure Management Description: Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure <140/90mmHg OR patients with a blood pressure ≥140/90mmHg and prescribed 2 or more anti-hypertensive medications during the most recent office visit.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*		New	Clinical Process/Effectiveness.

** PQRS = Physician Quality Reporting System.
EHR PQRS = Physician Quality Reporting System's Electronic Health Record Reporting Option.
CHIPRA = Children's Health Insurance Program Reauthorization Act.
HEDIS = Healthcare Effectiveness Data and Information Set.
ACA 2701 = Affordable Care Act section 2701.
NCQA–PCMH = National Committee for Quality Assurance—Patient Centered Medical Home.
Group Reporting PQRS = Physician Quality Reporting System's Group Reporting Option.
UDS = Uniform Data System (Health Resources Services Administration).
ACO = Accountable Care Organization (Medicare Shared Savings Program).

6. Proposed Reporting Methods for Clinical Quality Measures for Eligible Professionals

(a) Proposed Reporting Methods for Medicaid EPs

For Medicaid EPs, States are, and will continue in Stage 2 to be, responsible for determining whether and how electronic reporting would occur, or whether they wish to allow reporting through attestation. If a State does require such electronic reporting, the State is responsible for sharing the details on the process with its provider community. We anticipate that whatever means States have deployed for capturing Stage 1 clinical quality measures electronically would be similar for reporting in CY 2013. However, we note that subject to our prior approval, this is within the States' purview. Beginning in CY 2014, the States will establish the method and requirements, subject to CMS prior approval, for electronically reporting.

(b) Proposed Reporting Methods for Medicare EPs in CY 2013

In the CY 2012 Medicare Physician Fee Schedule final rule, we established a pilot program for Medicare EPs for CY 2012 that is intended to test and demonstrate our capacity to accept electronic reporting of Stage 1 clinical quality measure data (76 FR 73422 through 73425). The title of this pilot program is the Physician Quality Reporting System—Medicare EHR Incentive Pilot, and it capitalizes on existing quality measures reporting infrastructure. The EHR Incentive Program Registration and Attestation System is located at *https://ehrincentives.cms.gov/hitech/login.action*.

(c) Proposed Reporting Methods for Medicare EPs Beginning With CY 2014

Under section 1848(o)(2)(A)(iii) of the Act, EPs must submit information on the clinical quality measures selected by the Secretary ''in a form and manner specified by the Secretary'' as part of demonstrating meaningful use of Certified EHR Technology. As discussed in section II.B.4.b. of this proposed rule, Medicare EPs who are in their first year of Stage 1 may report clinical quality measures through attestation for a continuous 90-day EHR reporting period (for an explanation of reporting through attestation, see the discussion in the Stage 1 final rule (75 FR 44430 through 44431)).

Medicare EPs who choose to report 12 clinical quality measures as described in Options 1.a. and 1.b. in section II.B.4.c. of this proposed rule would submit

through an aggregate reporting method, which would require the EP to log into a CMS-designated portal. Once the EP has logged into the portal, they would be required to submit through an upload process, data produced as output from their Certified EHR Technology in an XML-based format specified by CMS.

We are considering an ''interim submission'' option for Medicare EPs who are in their first year of Stage 1 and who participate in the Physician Quality Reporting System. Under this option, EPs would submit the Physician Quality Reporting System clinical quality measures data for a continuous 90-day EHR reporting period, and the data must be received no later than October 1 to meet the requirements of the EHR Incentive Program. The EP would report the remainder of his/her clinical quality measures data by the deadline specified for the Physician Quality Reporting System to meet the requirements of the Physician Quality Reporting System. We request public comment on this potential option. Medicare EPs who are beyond their first year of Stage 1 and who choose the Physician Quality Reporting System EHR reporting option (Option 2 in section II.B.4.(c). of this proposed rule) must report in the form and manner specified for the Physician Quality Reporting System (for more information on current reporting requirements, see the CY 2012 Medicare Physician Fee Schedule final rule with comment period (76 FR 73314)).

(d) Group Reporting Option for Medicare and Medicaid Eligible Professionals Beginning With CY 2014

For Stage 1, EPs were required to report the clinical quality measures on an individual basis and did not have an option to report the measures as part of a group practice. Under section 1848(o)(2)(A) of the Act, the Secretary may provide for the use of alternative means for eligible professionals furnishing covered professional services in a group practice (as defined by the Secretary) to meet the requirements of meaningful use. Beginning with CY 2014, we are proposing three group reporting options to allow eligible professionals within a single group practice to report clinical quality measure data on a group level. All three methods would be available for Medicare EPs, while only the first one would be possible for Medicaid EPs, at States' discretion.

We are proposing each of these options as an alternative to reporting clinical quality measure data as an individual eligible professional under the proposed options and reporting methods discussed earlier in this rule. These group reporting options would only be available for reporting clinical quality measures for purposes of the EHR Incentive Program and only if all EPs in the group are beyond the first year of Stage 1. EPs would not be able to use these group reporting options for any of the other meaningful use objectives and associated measures in the EHR Incentive Programs.

The three group reporting options that we propose for EPs are as follows:

- Two or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) may be considered an EHR Incentive Group for the purposes of reporting clinical quality measures for the Medicare EHR Incentive Program. This group reporting option is only available for electronic reporting of clinical quality measures and is not available for those EPs in their first year of Stage 1. The clinical quality measures reported under this option would represent all EPs within the group. EPs who choose this group reporting option for clinical quality measures must still individually satisfy the objectives and associated measures for their respective stage of meaningful use. CMS proposes that States may also choose this option to accept group reporting for clinical quality measures, based upon a pre-determined definition of a ''group practice,'' such as sharing one TIN.
- Medicare EPs participating in the Medicare Shared Savings Program and the testing of the Pioneer Accountable Care Organization (ACO) model who use Certified EHR Technology to submit ACO measures in accordance with the requirements of the Medicare Shared Savings Program would be considered to have satisfied their clinical quality measures reporting requirement as a group for the Medicare EHR Incentive Program. The Medicare Shared Savings Program does not require the use of Certified EHR Technology. However, all clinical quality measures data must be extracted from Certified EHR Technology in order for the EP to qualify for the Medicare EHR Incentive Program if an EP intends to use this group reporting option. EPs must still individually satisfy the objectives and associated measures for their respective stage of meaningful use, in addition to submitting clinical quality measures as part of an ACO. EPs who are part of an ACO but do not enter the data used for reporting the clinical quality measures (which excludes the survey tool or claims-based measures that are collected to calculate the quality performance score in the Medicare Shared Savings Program) into Certified EHR Technology would not be able to meet meaningful use requirements. (For more information about the requirements of the Medicare Shared Savings Program, see 42 CFR part 425 and the final rule published at 76 FR 67802). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the Medicare Shared Savings Program that may apply in the future. EPs must be part of a group practice (that is, two or more eligible professionals, each identified with a unique NPI associated with a group practice identified under one TIN) to be able to use this group reporting option.
- Medicare EPs who satisfactorily report Physician Quality Reporting System clinical quality measures using Certified EHR Technology under the Physician Quality Reporting System Group Practice Reporting Option, would be considered to have satisfied their clinical quality measures reporting requirement as a group for the Medicare EHR Incentive Program. For more information about the Physician Quality Reporting System Group Practice Reporting Option, see 42 CFR 414.90 and the CY 2012 Medicare Physician Fee Schedule final rule (76 FR 73314). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the Physician Quality Reporting System Group Practice Reporting Option that may apply in the future and must still individually satisfy the objectives and associated measures for their respective stage of meaningful use.

States would have the option to allow group reporting of clinical quality measures based upon the first option previously described, through an update to their State Medicaid HIT Plan, and would have to address how they would address the issue of EPs who switch group practices during an EHR reporting period.

7. Proposed Clinical Quality Measures for Eligible Hospitals and Critical Access Hospitals

(a) Statutory and Other Considerations

Sections 1886(n)(3)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of clinical quality measures by eligible hospitals and CAHs as part of demonstrating meaningful use of Certified EHR Technology. For further explanation of the statutory requirements, we refer readers to the discussion in our Stage 1 proposed and final rules (75 FR 1870 through 1902 and 75 FR 44380 through 44435, respectively).

Section 1886(n)(3)(B)(i)(I) of the Act requires the Secretary to give preference to clinical quality measures that have been selected for the purpose of applying section 1886(b)(3)(B)(viii) of the Act (that is, measures that have been selected for the Hospital Inpatient Quality Reporting (IQR) Program) or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) (namely, the NQF). We are proposing clinical quality measures for eligible hospitals and CAHs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference, although we note that the Act does not require the selection of such measures for the EHR Incentive Programs. Measures listed in this proposed rule that do not have an NQF identifying number are not NQF endorsed.

Under section 1903(t)(8) of the Act, the Secretary must seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments for eligible hospitals and CAHs to demonstrate meaningful use of Certified EHR Technology under Medicare and Medicaid. Therefore, to meet this requirement, we continue our practice from Stage 1 of proposing clinical quality measures that would apply for both the Medicare and Medicaid EHR Incentive Programs, as listed in sections II.B.6.(b). and II.B.6.(c). of this proposed rule.

In accordance with CMS and HHS quality goals as well as the HHS National Quality Strategy recommendations, the hospital clinical quality measures that we are proposing beginning with FY 2014 can be categorized into the following six domains, which are described in section II.B.3. of this proposed rule:

- Clinical Process/Effectiveness.
- Patient Safety.
- Care Coordination.
- Efficient Use of Healthcare Resources.
- Patient & Family Engagement.
- Population & Public Health.

The selection of clinical quality measures we are proposing for eligible hospitals and CAHs was based on statutory requirements, the HITPC's recommendations, alignment with other CMS and national hospital quality measurement programs such as the Joint Commission, the Medicare Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program, the National Quality Strategy, and other considerations discussed in sections II.B.6.(b). and II.B.6.(c). of this proposed rule. The proposed reporting methods for Medicare eligible hospitals and CAHs are described in sections II.B.7.(a). and II.B.7.(b). of this proposed rule. The proposed reporting methods for Medicaid-only eligible hospitals are described in section II.B.7.(c). of this proposed rule.

Section 1886(n)(3)(B)(iii) of the Act requires that in selecting measures for eligible hospitals and CAHs, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required. In consideration of the importance of alignment with other measure sets that apply to eligible hospitals and CAHs, we have analyzed the Hospital IQR Program, hospital measures used by State Medicaid agencies, and the Joint Commission's hospital quality measures when selecting the measures to be reported under the EHR Incentive Program. Furthermore, we have placed emphasis on those measures that are in line with the National Quality Strategy and the HITPC's recommendations.

(b) Proposed Clinical Quality Measures for Eligible Hospitals and CAHs for FY 2013

For the EHR reporting periods in FY 2013, we propose that the eligible hospitals and CAHs would be required to submit information on each of the 15 clinical quality measures that were finalized for FYs 2011 and 2012 in the Stage 1 final rule (75 FR 44418 through 44420, Table 10). We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those clinical quality measures (75 FR 44411 through 44422).

(c) Clinical Quality Measures Proposed for Eligible Hospitals and CAHs Beginning With FY 2014

We are proposing to change the reporting requirement beginning with FY 2014 to require eligible hospitals and CAHs to report 24 clinical quality measures from a menu of 49 clinical quality measures, including at least 1 clinical quality measure from each of the 6 domains. The 49 clinical quality measures would include the current set of 15 clinical quality measures that were finalized for FYs 2011 and 2012 in the Stage 1 final rule as well as additional pediatric measures, an obstetric measure, and cardiac measures.

Our experience from Stage 1 in implementing the current set of 15 clinical quality measures in specialty and low volume eligible hospitals has illuminated several challenges. For example, children's hospitals rarely see patients 18 years or older. One of the exceptions to this generality is individuals with sickle cell disease. National Institutes of Health Guidelines (NIH Publication 02–2117) list the conditions under which thrombolytic therapy cannot be recommended for adults or children with sickle cell disease. This, plus the fact that children's hospitals have on average two or fewer cases of stroke per year, have created workflow, cost, and clinical barriers to demonstrating meaningful use as it relates to the clinical quality measures for stroke and VTE. We are considering whether a case number threshold would be appropriate, given the apparent burden on hospitals that very seldom have the types of cases addressed by certain measures. Hospitals that do not have enough cases to exceed the threshold would be exempt from reporting certain clinical quality measures. We solicit comments on what the numerical range of threshold should be, how hospitals would demonstrate to CMS or State Medicaid agencies that they have not exceeded this threshold, whether it should apply to only certain hospital clinical quality measures (and if so, which ones), and the extent of the burden on hospitals if a case number threshold is not adopted (given that they are allowed to report ''zeros'' for the measures). We are also soliciting comment on limiting the case threshold exemption to only children's, cancer hospitals, and a subset of hospitals in the Indian health system as they have a much more narrow patient base than acute care and critical access hospitals. Comments are solicited for application of the thresholds to Stage 1 of meaningful use in 2013, as the issue would be mitigated for Stages 1 and 2 by a beginning in 2014 proposed menu set of hospital clinical quality measures.

Aside from the previous threshold discussion, we are proposing clinical quality measures in Table 9 that would apply for all eligible hospitals and CAHs beginning with FY 2014, regardless of whether an eligible hospital or CAH is in Stage 1 or Stage 2 of meaningful use. We propose that eligible hospitals and CAHs must report a total of 24 clinical quality measures from those listed in Table 9. Eligible hospitals and CAHs would have to select and report at least 1 measure from each of the following 6 domains:

- Patient and Family Engagement.
- Patient Safety.
- Care Coordination.
- Population and Public Health.
- Efficient Use of Healthcare Resources.
- Clinical Process/Effectiveness.

For the remaining clinical quality measures, eligible hospitals and CAHs

would select and report the measures from Table 9 that best apply to their patient mix. We are soliciting comment on the number of measures and the appropriateness of the measures and domains for eligible hospitals and CAHs.

If an eligible hospital's or CAH's Certified EHR Technology does not contain patient data for at least 24 measures, including a minimum of at least 1 from each domain, then the eligible hospital or CAH must report the measures for which there is patient data and report the remaining required measures as ''zero denominators'' through the form and manner specified by the Secretary. In the unlikely event that there are no measures applicable to the eligible hospital's or CAH's patient mix, eligible hospitals or CAHs must still report 24 measures even if zero is the result in either the numerator or the denominator of the measure. If all measures have a value of zero from their Certified EHR Technology, then eligible hospitals or CAHs must report any 24 of the measures.

In the Stage 1 final rule (75 FR 44418), the title for the clinical quality measure NQF #438 was listed as ''Ischemic or hemorrhagic stroke—Antithrombotic therapy by day 2.'' The corrected measure title, which is also included in Table 9 is ''Stroke-5 Ischemic stroke—Antithrombotic therapy by day 2.''

Table 9 lists all of the clinical quality measures that we are proposing for eligible hospitals and CAHs to report for the EHR Incentive Programs beginning with FY 2014. The measures titles and descriptions in Table 9 reflect the most current updates, as provided by the measure stewards who are responsible for maintaining and updating the measure specifications, and therefore may not reflect the title and/or description as presented on the NQF Web site. Measures which are designated as ''New'' in the ''New Measures'' column were not finalized in the Stage 1 final rule. Some of the clinical quality measures in this table will require the development of electronic specifications. Therefore, we propose to consider these clinical quality measures for possible inclusion beginning with FY 2014 based on our expectation that their electronic specifications will be available at the time of or within a reasonable period the publication of the final rule. All clinical quality measure specification updates, including a schedule for updates to electronic specifications, would be posted on the EHR Incentive Program Web site (*https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp*), and we would notify the public.

Additionally, some of these measures have been submitted by the measure steward and are currently under review for endorsement consideration by the National Quality Forum. The finalized list of clinical quality measures that would apply for eligible hospitals and CAHs beginning with FY 2014 will be published in the final rule.

TABLE 9—CLINICAL QUALITY MEASURES PROPOSED FOR ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS BEGINNING WITH FY 2014

NQF #	Title	Measure steward and contact information	Other quality measure programs that use the same measure ***	New measure	Domain
0495	Title: Emergency Department (ED)-1 Emergency Department Throughput—Median time from ED arrival to ED departure for admitted ED patients. Description: Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department..	Oklahoma Foundation for Medical Quality (OFMQ) *www.ofmq.com* and click on ''Contact''.	IQR		Patient and Family Engagement.
0497	Title: ED-2 Emergency Department Throughput—admitted patients—Admit decision time to ED departure time for admitted patients. Description: Median time from admit decision time to time of departure from the emergency department for emergency department patients admitted to inpatient status.	Oklahoma Foundation for Medical Quality (OFMQ) *www.ofmq.com* and click on ''Contact''.	IQR		Patient and Family Engagement.
0435	Title: Stroke-2 Ischemic stroke—Discharged on anti-thrombotic therapy. Description: Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Clinical Process/Effectiveness.
0436	Title: Stroke-3 Ischemic stroke—Anticoagulation Therapy for Atrial Fibrillation/Flutter. Description: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Clinical Process/Effectiveness.
0437	Title: Stroke-4 Ischemic stroke—Thrombolytic Therapy Description: Acute ischemic stroke patients who arrive at this hospital within 2 hours (120 minutes) of time last known well and for whom IV t-PA was initiated at this hospital within 3 hours (180 minutes) of time last known well.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Clinical Process/Effectiveness.
0438	Title: Stroke-5 Ischemic stroke—Antithrombotic therapy by end of hospital day two. Description: Ischemic stroke patients administered antithrombotic therapy by the end of hospital day two.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Clinical Process/Effectiveness.
0439	Title: Stroke-6 Ischemic stroke—Discharged on Statin Medication Description: Ischemic stroke patients with LDL greater than or equal to 100 mg/dL, or LDL not measured, or, who were on a lipid-lowering medication prior to hospital arrival are prescribed statin medication at hospital discharge.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Clinical Process/Effectiveness.
0440	Title: Stroke-8 Ischemic or hemorrhagic stroke—Stroke education Description: Ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay addressing all of the following: Activation of emergency medical system, need for follow-up after discharge, medications prescribed at discharge, risk factors for stroke, and warning signs and symptoms of stroke.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Patient & Family Engagement.
0441	Title: Stroke-10 Ischemic or hemorrhagic stroke—Assessed for Rehabilitation. Description: Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Care Coordination.
0371	Title: Venous Thromboembolism (VTE)-1 VTE prophylaxis Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Patient Safety.

TABLE 9—CLINICAL QUALITY MEASURES PROPOSED FOR ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS BEGINNING WITH FY 2014—Continued

NQF #	Title	Measure steward and contact information	Other quality measure programs that use the same measure ***	New measure	Domain
0372	Title: VTE-2 Intensive Care Unit (ICU) VTE prophylaxis Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR		Patient Safety.
0373	Title: VTE-3 VTE Patients with Overlap of Anticoagulation Therapy Description: This measure assesses the number of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they must be discharged on both medications. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) = 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0374	Title: VTE Patients Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitored by Protocol (or Nomogram). Description: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0375	Title: VTE-5 VTE discharge instructions Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, to home with home health, or home hospice on warfarin with written discharge instructions that address all four criteria: Compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Patient and Family Engagement.
0376	Title: VTE-6 Incidence of potentially preventable VTE Description: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Patient Safety.
0132	Title: AMI-1-Aspirin at arrival for acute myocardial infarction (AMI) Description: Percentage of acute myocardial infarction (AMI) patients without aspirin contraindications who received aspirin within 24 hours before or after hospital arrival.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, TJC	New	Clinical Process/Effectiveness.
0142	Title: AMI-2-Aspirin Prescribed at Discharge for AMI Description: Percentage of acute myocardial infarction (AMI) patients without aspirin contraindications who are prescribed aspirin at hospital discharge.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0469	Title: Elective Delivery Prior to 39 Completed Weeks Gestation Description: Percentage of babies electively delivered prior to 39 completed weeks gestation.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	TJC		Clinical Process/Effectiveness.
0137	Title: AMI-3-ACEI or ARB for Left Ventricular Systolic Dysfunction-Acute Myocardial Infarction (AMI) Patients. Description: Percentage of acute myocardial infarction (AMI) patients with left ventricular systolic dysfunction (LVSD) and without both Angiotensin converting enzyme inhibitor (ACEI) and Angiotensin receptor blocker (ARB) contraindications who are prescribed an ACEI or ARB at hospital discharge. For purposes of this measure, LVSD is defined as chart documentation of a left ventricular ejection fraction (LVEF) less than 40% or a narrative description of left ventricular systolic (LVS) function consistent with moderate or severe systolic dysfunction.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0160	Title: AMI-5-Beta Blocker Prescribed at Discharge for AMI Description: Percentage of acute myocardial infarction (AMI) patients without beta blocker contraindications who are prescribed a beta blocker at hospital discharge.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0164	Title: AMI-7a-Fibrinolytic Therapy received within 30 minutes of hospital arrival. Description: Percentage of acute myocardial infarction (AMI) patients receiving fibrinolytic therapy during the hospital stay and having a time from hospital arrival to fibrinolysis of 30 minutes or less.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Clinical Process/Effectiveness.
0163	Title: AMI-8a-Primary Percutaneous Coronary Intervention (PCI) Description: Percentage of acute myocardial infarction (AMI) patients receiving percutaneous coronary intervention (PCI) during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Clinical Process/Effectiveness.
0639	Title: AMI-10 Statin Prescribed at Discharge Description: Percent of acute myocardial infarction (AMI) patients 18 years of age or older who are prescribed a statin medication at hospital discharge.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0148	Title: PN-3b-Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital. Description: Percentage of pneumonia patients 18 years of age and older who have had blood cultures performed in the emergency department prior to initial antibiotic received in hospital.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Efficient Use of Healthcare Resources.
0147	Title: PN-6-Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients. Description: Percentage of pneumonia patients 18 years of age or older selected for initial receipts of antibiotics for community-acquired pneumonia (CAP).	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Efficient Use of Healthcare Resources.

TABLE 9—CLINICAL QUALITY MEASURES PROPOSED FOR ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS BEGINNING WITH FY 2014—Continued

NQF #	Title	Measure steward and contact information	Other quality measure programs that use the same measure ***	New measure	Domain
0527	Title: SCIP-INF-1 Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision. Description: Surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision. Patients who received Vancomycin or a Fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within 2 hours prior to surgical incision. Due to the longer infusion time required for Vancomycin or a Fluoroquinolone, it is acceptable to start these antibiotics within 2 hours prior to incision time.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Patient Safety.
0528	Title: SCIP-INF-2-Prophylactic Antibiotic Selection for Surgical Patients. Description: Surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure).	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Efficient Use of Healthcare Resources.
0529	Title: SCIP-INF-3-Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time. Description: Surgical patients whose prophylactic antibiotics were discontinued within 24 hours after Anesthesia End Time. The Society of Thoracic Surgeons (STS) Practice Guideline for Antibiotic Prophylaxis in Cardiac Surgery (2006) indicates that there is no reason to extend antibiotics beyond 48 hours for cardiac surgery and very explicitly states that antibiotics should not be extended beyond 48 hours even with tubes and drains in place for cardiac surgery.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP, State use	New	Efficient Use of Healthcare Resources.
0300	Title: SCIP-INF-4-Cardiac Patients with Controlled 6 AM Postoperative Serum Glucose. Description: Percentage of cardiac surgery patients with controlled 6 a.m. serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Clinical Process/Effectiveness.
0301	Title: SCIP-INF-6-Surgery patients with appropriate hair removal Description: Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical hair site removal.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Patient Safety.
0453	Title: SCIP-INF-9-Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero. Description: Surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, TJC	New	Patient Safety.
0136	Title: HF-1 Heart Failure (HF): Detailed Discharge Instructions Description: Percentage of heart failure patients discharged home with written instructions or educational material given to patient or caregiver at discharge or during the hospital stay addressing all of the following: Activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Patient & Family Engagement.
0434	Title: Stroke-1 Venous Thromboembolism (VTE) Prophylaxis Description: Ischemic or a hemorrhagic stroke patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Patient Safety.
0284	Title: SCIP-Card-2 Surgery Patients on a Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker During the Perioperative Period. Description: Percentage of patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Clinical Process/Effectiveness.
0218	Title: SCIP-VTE-2 Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 hours Prior to Surgery to 24 Hours After Surgery End Time. Description: Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	IQR, HVBP	New	Patient Safety.
0496	Title: ED-3 Description: Median time from ED arrival to ED departure for discharged ED patients. Description: Median time from emergency department arrival to time of departure from the emergency room for patients discharged from the emergency department.	Oklahoma Foundation for Medical Quality (OFMQ) *www.ofmq.com* and click on ''Contact''.	OQR	New	Care Coordination.
0338	Title: Home Management Plan of Care Document Given to Patient/Caregiver. Description: Documentation exists that the Home Management Plan of Care (HMPC) as a separate document, specific to the patient, was given to the patient/caregiver, prior to or upon discharge.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	State use	New	Patient & Family Engagement.
0341	Title: PICU Pain Assessment on Admission Description: Percentage of PICU patients receiving: a. Pain assessment on admission, b. Periodic pain assessment.	National Association of Children's Hospitals and Related Institutions (NACHRI) *www.nachri.org* and click on ''Contact Us''.	State use	New	Patient & Family Engagement.
0342	Title: PICU Periodic Pain Assessment Description: Percentage of PICU patients receiving: a. Pain assessment on admission, b. Periodic pain assessment.	National Association of Children's Hospitals and Related Institutions (NACHRI) *www.nachri.org* and click on ''Contact Us''.	State use	New	Patient & Family Engagement.

TABLE 9—CLINICAL QUALITY MEASURES PROPOSED FOR ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS BEGINNING WITH FY 2014—Continued

NQF #	Title	Measure steward and contact information	Other quality measure programs that use the same measure ***	New measure	Domain
0480	Title: Exclusive Breastfeeding at Hospital Discharge Description: Exclusive Breastfeeding (BF) for the first 6 months of neonatal life has long been the expressed goal of WHO, DHHS, APA, and ACOG. ACOG has recently reiterated its position (ACOG 2007). A recent Cochrane review substantiates the benefits (Kramer, 2002). Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) BF (Shealy, 2005; Taveras, 2004; Petrova, 2007; CDC-MMWR, 2007). Exclusive Breastfeeding rate during birth hospital stay has been calculated by the California Department of Public Health for the last several years using newborn genetic disease testing data. HP2010 and the CDC have also been active in promoting this measure. Holding prenatal and intrapartum providers accountable is an important way to incent greater efforts during the critical prenatal and immediate postpartum periods where BF attitudes are solidified.	California Maternal Quality Care Collaborative *www.cmqcc.org* and click on ''Contact Us''.	State use	New	Clinical Process/Effectiveness.
0481	Title: First temperature measured within one hour of admission to the NICU. Description: Percent of NICU admissions with a birth weight of 501–1500g with a first temperature taken within 1 hour of NICU admission.	Vermont Oxford Network *www.vtoxford.org* and click on ''Contact Us''.	State use	New	Clinical Process/Effectiveness.
0482	Title: First NICU Temperature < 36 degrees C Description: Percent of all NICU admissions with a birth weight of 501–1500g whose first temperature was measured within one hour of admission to the NICU and was below 36 degrees Centigrade.	Vermont Oxford Network *www.vtoxford.org* and click on ''Contact Us''.	State use	New	Clinical Process/Effectiveness.
0143	Title: Use of relievers for inpatient asthma Description: Percentage of pediatric asthma inpatients, age 2–17, who were discharged with a principal diagnosis of asthma who received relievers for inpatient asthma.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	State use	New	Clinical Process/Effectiveness.
0144	Title: Use of systemic corticosteroids for inpatient asthma Description: Percentage of pediatric asthma inpatients (age 2–17 years) who were discharged with principal diagnosis of asthma who received systemic corticosteroids for inpatient asthma.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	State use	New	Clinical Process/Effectiveness.
0484	Title: Proportion of infants 22 to 29 weeks gestation treated with surfactant who are treated within 2 hours of birth. Description: Number of infants 22 to 29 weeks gestation treated with surfactant within 2 hours of birth.	Vermont Oxford Network *www.vtoxford.org* and click on ''Contact Us''.	State use	New	Clinical Process/Effectiveness.
0716	Title: Healthy Term Newborn Description: Percent of term singleton livebirths (excluding those with diagnoses originating in the fetal period) who DO NOT have significant complications during birth or the nursery care.	California Maternal Quality Care Collaborative *www.cmqcc.org* and click on ''Contact Us''.	State use	New	Patient Safety.
1354	Title: Hearing screening prior to hospital discharge (EHDI-1a) Description: This measure assesses the proportion of births that have been screened for hearing loss before hospital discharge.	CDC *www.cdc.gov* and click on ''Contact CDC''.	State use	New	Clinical Process/Effectiveness.
1653	Title: IMM-1 Pneumococcal Immunization (PPV23) Description: This prevention measure addresses acute care hospitalized inpatients 65 years of age and older (IMM-1b) AND inpatients aged between 6 and 64 years (IMM-1c) who are considered high risk and were screened for receipt of 23-valent pneumococcal polysaccharide vaccine (PPV23) and were vaccinated prior to discharge if indicated. The numerator captures two activities; screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to PPV23, patients who were offered and declined PPV23 and patients who received PPV23 anytime in the past are captured as numerator events.	Oklahoma Foundation for Medical Quality (OFMQ) *www.ofmq.com* and click on ''Contact''.	IQR	New	Population/Public Health.
1659	Title: IMM-2 Influenza Immunization Description: This prevention measure addresses acute care hospitalized inpatients age 6 months and older who were screened for seasonal influenza immunization status and were vaccinated prior to discharge if indicated. The numerator captures two activities: Screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to the vaccine, patients who were offered and declined the vaccine and patients who received the vaccine during the current year's influenza season but prior to the current hospitalization are captured as numerator events. Influenza (flu) is an acute, contagious, viral infection of the nose, throat and lungs (respiratory illness) caused by influenza viruses. Outbreaks of seasonal influenza occur annually during late autumn and winter months although the timing and severity of outbreaks can vary substantially from year to year and community to community. Influenza activity most often peaks in February, but can peak rarely as early as November and as late as April. In order to protect as many people as possible before influenza activity increases, most flu-vaccine is administered in September through November, but vaccine is recommended to be administered throughout the influenza season as well. Because the flu vaccine usually first becomes available in September, health systems can usually meet public and patient needs for vaccination in advance of widespread influenza circulation.	Oklahoma Foundation for Medical Quality (OFMQ) *www.ofmq.com* and click on ''Contact''.	IQR	New	Population/Public Health.

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IQR = Inpatient Quality Reporting.
TJC = The Joint Commission.
HVBP = Hospital Value-Based Purchasing.
OQR = Outpatient Quality Reporting.

8. Proposed Reporting Methods for Eligible Hospitals and Critical Access Hospitals

(a) Reporting Methods in FY 2013

In the CY 2012 Hospital Outpatient Prospective Payment System (OPPS) final rule with comment period (76 FR 74122), we implemented a pilot program for Medicare eligible hospitals and CAHs for 2012 that is intended to test and demonstrate our capacity to accept electronic reporting of clinical quality measure information. The title of this pilot program is the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs. The EHR Incentive Program Registration and Attestation System is located at *https://ehrincentives.cms.gov/hitech/login.action*.

(b) Reporting Methods Beginning With FY 2014

Under section 1886(n)(3)(A)(iii) of the Act, eligible hospitals and CAHs must submit information on the clinical quality measures selected by the Secretary ''in a form and manner specified by the Secretary'' as part of demonstrating meaningful use of Certified EHR Technology. Medicare eligible hospitals and CAHs that are in their first year of Stage 1 of meaningful use may report the 24 clinical quality measures from Table 9 through attestation for a continuous 90-day EHR reporting period as described in section II.B.1. of this proposed rule. Readers should refer to the discussion in the Stage 1 final rule for more information about reporting clinical quality measures through attestation (75 FR 44430 through 44431). Medicare eligible hospitals and CAHs would select one of the following two options for submitting clinical quality measures electronically.

- Option 1: Submit the selected 24 clinical quality measures through a CMS-designated portal.

For this option, the clinical quality measures data would be submitted in an XML-based format on an aggregate basis reflective of all patients without regard to payer. This method would require the eligible hospitals and CAHs to log into a CMS-designated portal. Once the eligible hospitals and CAHs have logged into the portal, they would be required to submit through an upload process, data that is based on specified structures produced as output from their Certified EHR Technology.

- Option 2: Submit the selected 24 clinical quality measures in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using Certified EHR Technology.

We propose that, as an alternative to the aggregate-level reporting schema described previously under Option 1, Medicare eligible hospitals and CAHs that successfully report measures in an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using Certified EHR Technology would satisfy their clinical quality measures reporting requirement under the Medicare EHR Incentive Program. Please refer to the CY 2012 OPPS final rule (76 FR 74489 through 74492) for details on the pilot. We are considering an ''interim submission'' option for Medicare eligible hospitals and CAHs that are in their first year of Stage 1 beginning in FY 2014 and available in subsequent years through an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs. Under this option, eligible hospitals and CAHs would submit clinical quality measures data for a continuous 90-day EHR reporting period, and the data must be received no later than July 1 to meet the requirements of the EHR Incentive Program. We request public comment on this potential option.

We are considering the following 4 options of patient population—payer data submission characteristics:

- All patients—Medicare only.
- All patients—all payer.
- Sampling—Medicare only, or
- Sampling—all payer.

Currently, the Hospital IQR program uses the ''sampling—all payer'' data submission characteristic. We request public comment on each of these 4 sets of characteristics and the impact they may have to vendors and hospitals, including but not limited to potential issues with the respective size of data files for each characteristic. We intend to select 1 of the 4 sets as the data submission characteristic for the electronic reporting method for eligible hospitals and CAHs beginning in FY 2014.

We note that the Hospital IQR program does not currently have an electronic reporting mechanism. We invite comment on whether an electronic reporting option would be appropriate for the Hospital IQR Program and whether it would provide further alignment with the EHR Incentive Program.

(c) Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals

States that have launched their Medicaid EHR Incentive Programs plan to collect clinical quality measures electronically from Certified EHR Technology used by eligible hospitals. Each State is responsible for sharing the details on the process for electronic reporting with its provider community. We anticipate that whatever means States have deployed for capturing Stage 1 clinical quality measures electronically will be similar for Stage 2. However, we note that subject to our prior approval, the process, requirements, and the timeline is within the States' purview.

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

We propose to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR incentive programs. The demonstration methods we adopt for Medicare would automatically be available to the States for use in their Medicaid programs. The Medicare methods are segmented into clinical quality measures and meaningful use objectives.

b. Methods for Demonstration of the Stage 2 Criteria of Meaningful Use

We do not propose changes to the attestation process for Stage 2 meaningful use objectives, except the group reporting option discussed in section II.C.1.c. of this proposed rule. Several changes are proposed for clinical quality measure reporting, as discussed in section II.B.3. of this proposed rule. An EP, eligible hospital or CAH must successfully attest to the Stage 2 meaningful use objectives and successfully submit clinical quality measures to be a meaningful EHR user. We would revise § 495.8 to accommodate the Stage 2 objective and measures, as well as changes we are making to Stage 1.

As HIT matures we expect to base demonstration more on automated reporting by certified EHR technologies, such as the direct electronic reporting of measures both clinical and nonclinical and documented participation in HIE. As HIT advances we expect to move more of the objectives away from being demonstrated through attestation. However, at this time we do not believe that the advances in HIT and the certification of EHR technologies allow us to propose an alternative to attestation in this proposed rule. We continue to evaluate the possible alternatives to attestation and the changes to certification and/or

meaningful use. As discussed later, while we would continue to require analysis of all meaningful use measures at the individual EP, eligible hospital or CAH level, we are proposing a batch file process in lieu of individual Medicare EP attestation through the CMS Attestation Web site beginning with CY 2014. This batch reporting process will ensure that meaningful use of certified EHR technology continues to be measured at the individual level, while promoting efficiencies for group practices that must submit attestations on large groups of individuals.

We would continue to leave open the possibility for CMS and/or the States to test options to utilize existing and emerging HIT products and infrastructure capabilities to satisfy other objectives of the meaningful use definition. The optional testing could involve the use of registries or the direct electronic reporting of some measures associated with the objectives of the meaningful use definition. We would not require any EP, eligible hospital or CAH to participate in this testing in either 2013 or 2014 in order to receive an incentive payment or avoid the payment adjustment.

c. Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning With CY 2014

For Stage 1, EPs were required to attest and report on core and menu objectives on an individual basis and did not have an option to report collectively with other EPs in the same group practice. Under section 1848(o)(2)(A) of the Act, the Secretary may provide for the use of alternative means for eligible professionals furnishing covered professional services in a group practice (as defined by the Secretary) to meet the requirements of meaningful use. For EHR reporting periods occurring in CY 2014 and subsequent years, we are proposing a group reporting option to allow Medicare EPs within a single group practice to report core and menu objective data through a batch file process in lieu of individual Medicare EP attestation through the CMS Attestation Web site. The purpose of proposing a group reporting option is to provide administrative relief to group practices that have large numbers of EPs who need to attest to meaningful use. This option is intended to allow a batch reporting of each individual EP's core and menu objective data, and each EP would still have to meet the required meaningful use thresholds independently. This option does not permit any EP to meet the required meaningful use thresholds through the use of a group average or any other method of group demonstration.

We would establish a file format in which groups would be required to submit core and menu objective information for individual Medicare EPs (including the stage of meaningful use the individual EP is in, numerator, denominator, exclusion, and yes/no information for each core and menu objective) and also establish a process through which groups would submit this batch file for upload.

States would have the option of offering batch reporting of meaningful use data for Medicaid EPs. States would need to outline their approach in their State Medicaid HIT Plan.

For purposes of this group reporting option, we propose to define a Medicare EHR Incentive Group as 2 or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) through the Provider Enrollment, Chain, and Ownership System (PECOS). This is the same definition as one proposed in the group reporting option of clinical quality measures. States choosing to exercise this option would have to clearly define a Medicaid EHR Incentive Group via their State Medicaid HIT Plan. None of the EPs in either a Medicare or Medicaid EHR Incentive Group could be hospital-based according to the definition for these programs (see 42 CFR 495.4). Any EP that successfully attests as part of one Medicare EHR Incentive Group would not be permitted to also attest individually or attest as part of a batch report for another Medicare EHR Incentive Group. Because EPs can only participate in either the Medicare or Medicaid incentive programs in the same payment year, an EP that is part of a Medicare EHR Incentive Group would not be able to receive a Medicaid EHR incentive payment or be included as part of a batch report for a Medicaid EHR Incentive Group.

This group reporting option would be limited to data for the core and menu objectives, but it would not include the reporting of clinical quality measures, which is also required in order to demonstrate meaningful use and receive an EHR incentive payment. Clinical quality measures must be reported separately through one of the electronic submission options that are described in section II.B. of this proposed rule. Because we are proposing multiple group reporting methods for clinical quality measures, EPs would not have to report core and menu objective data in the same EHR Incentive Group as they report their clinical quality measures. An EP would be able to submit the core and menu objectives as part of a group and the clinical quality measures as an individual or vice versa (that is, use clinical quality group reporting, while using individual reporting for the core/menu objectives).Please note that EPs would not be required to batch report as part of a group, and would still be permitted to attest individually through the CMS Attestation Web site (as long as they did not also report as part of a group). In order to demonstrate meaningful use and avoid any payment adjustments applicable under the Medicare EHR Incentive Program, EPs would be required to individually meet all of the thresholds of the core and menu objectives. In other words, an EP cannot avoid payment adjustments through the use of a group average or any other method of group demonstration. Payment adjustments would be applied to individual EPs, as described in section II.C. of this proposed rule and not to Medicare EHR Incentive Groups.

An EP's incentive payment would not be automatically assigned to the Medicare EHR Incentive Group with which they batch report under this option. The EP would still have to select the payee TIN during the registration process.

EPs that practice in multiple practices or locations would be responsible for submitting complete information for all actions taken at practices/locations equipped with Certified EHR Technology. Under 42 CFR 495.4, to be considered a meaningful EHR user, an EP must have 50 percent or more of their patient encounters in practice(s) or location(s) where Certified EHR Technology is available. In the July 28, 2010 final rule (75 FR 44329), we also made clear that an EP must include encounters for all locations equipped with Certified EHR Technology. We are not proposing to change these requirements in this rulemaking. Therefore, an EP who chooses the group reporting option would be required to include in such reporting core and menu objective information on all encounters where Certified EHR Technology is available, even if some encounters occurred at locations not associated with the EP's Medicare EHR Incentive Group. We are not proposing a minimum participation threshold for reporting as part of an EHR Incentive Group; in other words, an EP who is able to meet the 50 percent threshold of patient encounters in locations equipped with Certified EHR Technology could report all of their core

and menu objective data as part of an EHR Incentive Group in which they had only 5 percent of their patient encounters, provided they report all of the data from the other locations through the batch reporting process.

We also seek public comment on a group reporting option that allows groups an additional reporting option in which groups report for their EPs a whole rather than broken out by individual EP.

In the January 18, 2011 **Federal Register** (76 FR 2910), the Health IT Policy Committee published a request for comment, to which 422 organizations and individuals submitted comments. In it, the committee invited comment on the following question, ''Should Stage 2 allow for a group reporting option to allow group practices to demonstrate meaningful use at the group level for all EPs in that group?''

The majority of those responding to this question supported this approach as one reporting option for EPs. Commenters often cited that a group reporting option will reduce administrative burden. Many commenters expressed an opinion that permitting group reporting may harness EP competition that will improve performance with peers within the group practice. Furthermore, commenters also stated that this option would: Facilitate physician teamwork and care coordination, be helpful for specialists and community health centers, and highlight system-level performance, thus creating incentives to invest in system-wide improvement programs.

When commenting on the group reporting option we are providing the following list of suggested topics, but this list is by no means exhaustive:

- What should the definition of a group be for the exercise of group reporting? For example, under the PQRS Group Reporting Option, a group is defined as a physician group practice, as defined by a single Tax Payer Identification Number, with 25 or more individual eligible professionals who have reassigned their billing rights to the TIN. We could adopt this definition or an alternative definition.
- Should there be a self nomination process for groups as in PQRS or an alternative process for identifying groups?
- Regarding the availability of Certified EHR Technology across the group, should the group be required to utilize the same Certified EHR Technology?
- Should a group be eligible if Certified EHR Technology (same or different) is not available to all associated EPs at all locations?
- Should a group be eligible if they use multiple Certified EHR Technologies that cannot share data easily?
- With respect to EPs who practice in multiple groups or in a group and practice individually, how should meaningful use activities be calculated?
- As the HITECH Act requires all meaningful users to be paid 75 percent of all covered services, how should the covered services performed by EPs in another practice be assigned to the group TIN?
- How will meaningful use activities performed at other groups be included?
- Should these services be included in the attesting group, or should CMS just ignore this information or account for it in other ways?
- How should the government address an EPs failure to meet a measure individually?
- If an EP chooses not to participate in a particular objective should they be a meaningful EHR user under the group if their non-participation still allows group compliance with a percentage threshold?
- How should yes/no objectives be handled in this situation?
- Some EPs in a group participate in Medicaid while others participate in Medicare; what covered services should the meaningful use calculation capture?
- Incentive payment assignment.
- Should the incentive payment be reassigned to the group automatically or does the EP still need to assign it to the group at registration?
- Should the same policy exist if the EP has covered services billed to other TINs?
- How should covered services for EPs who leave a group during an active EHR reporting period be handled?
- How should payment adjustments for Group reporting be handled?
- What alternative options should be considered for reporting meaningful use, while capturing necessary data?

For options presented, please share how each would be effectively implemented while meeting the objectives of the statute. For example, should EPs continue to report individually, use the batch file process proposed in this proposed rule or be included in a report of all EP data combined under one TIN?

2. Data Collection for Online Posting, Program Coordination, and Accurate Payments

In addition to the data already being collected under our regulations (§ 495.10), we propose to collect the business email address of EPs, eligible hospitals and CAHs to facilitate communication with providers. We do not propose to post this information online. We propose to amend § 495.10 accordingly. We propose to begin collection as soon as the registration system can be updated following the publication of this final rule for both the Medicare and Medicaid EHR incentive programs.

We do not propose any changes to the registration for the Medicare and Medicaid EHR incentive programs, to the rules on EPs switching between programs, or to the record retention requirements in § 495.10.

3. Hospital-Based Eligible Professionals

We propose changes to the definition of a hospital-based eligible professional only to recognize the determination of hospital-based once Medicare providers are subject to payment adjustments. We refer readers to section II.D.2. of this proposed rule for that discussion.

While we are not proposing changes to the definition, we do seek comments on the following discussion. The definition of ''hospital-based'' in the Social Security Act discusses the eligible professional furnishing professional services ''through the use of the facilities and equipment, including qualified electronic health records, of the hospital'' (section 1903(t)(3)(D) and 1848(o)(1)(C)(ii) of the Act). In the Stage 1 final rule, we addressed comments on this portion of the definition (75 FR 44441). Nevertheless, during implementation of Stage 1, we have been asked about situations where clinicians may work in specialized hospital units, the clinicians have independently procured and utilize EHR technology that is completely distinct from that of the hospital, and the clinicians are capable, without the facilities and equipment of the hospital, of meeting the eligible professional (for example ambulatory, not in-patient) definition of meaningful use. These inquiries point out that such situations are uncommon and might not be generalized under the uniform definition used by place of service codes.

We solicit comments on this issue. Specifically, comments should address and provide documentation supporting whether specialized hospital units are using stand-alone certified EHR technology separate from that of the hospital. In addition, the comments should address (and we would request documentation on) whether EPs are using the facilities and equipment of the hospital. We consider hospital facilities and equipment to refer to the physical

environment needed to support the necessary hardware; internet access and firewalls; the hardware itself, including servers; and system interfaces necessary for demonstrating meaningful use, for example, to health information exchanges, laboratory information systems, or pharmacies.

Thus, comments should address whether EPs using stand-alone certified EHR technology separate from that of the hospital, are truly not accessing the facilities and equipment of the hospitals. We would appreciate discussions of EP workflow to demonstrate how the EPs avoid use of such facilities and equipment.

Were we to adopt a policy on this issue, we believe additional attestation elements would need to be added to the determination of whether an EP is hospital-based. Such attestations would be subject to audit and the False Claims Act. In addition, were we to adopt a policy on this issue, EPs found not to be hospital-based would not only be potentially eligible for incentive payments, but also subject to payment adjustments under Medicare.

We also request comments on whether the criteria for ambulatory EHRs and the meaningful use criteria that apply to EPs could be met in cases where EPs are primarily providing inpatient or Emergency Department services. By definition, the EPs affected by this issue are those who provide 90 percent or more of their services in the inpatient or emergency department, and who provide less than 10 percent of their services, and possibly none, in outpatient settings. However, since the beginning of the program, we have been clear that for EPs, meaningful use measures would not include patient encounters that occur within the inpatient or emergency departments (POS 21 or 23). See for example, FAQ 10068, 10466, and FAQ 10462.

We reiterate this policy in section II.A.3.d.(2). of this proposed rule, where we explain that all meaningful use policies for EPs apply only to outpatient settings (all settings except the inpatient and emergency department of a hospital). Some of our meaningful use criteria for EPs are measured based on office visits (clinical summaries) and others assume an outpatient type of setting (patient reminders). The certification rules at 45 CFR part 170 differentiate between ambulatory and inpatient EHRs, and it is unclear whether the EPs in this case would have inpatient or ambulatory technology. We request comments on this issue. Finally, we request comments as to whether patients affected by this situation would essentially be ''double-counted;'' once for the hospital's EHR incentive payment, and once for the EP's incentive payment, and whether and how this issue should be addressed, such as potentially excluding discharges associated with EPs who receive an incentive payment based upon the same inpatient.

4. Interaction With Other Programs

There are no proposed changes to the ability of providers to participate in the Medicare and Medicaid EHR incentive programs and other CMS programs. We continue to work on aligning the data collection and reporting of the various CMS programs, especially in the area of clinical quality measurement. See section II.B. of this proposed rule for the proposed alignment initiatives for clinical quality measures.

D. Medicare Fee-for-Service

1. General Background and Statutory Basis

As we discussed in the Stage 1 final rule (75 FR 44447), sections 4101(a) and 4102(a) of the HITECH Act amended sections 1848, 1886, and 1814(l) of the Act to provide for incentive payments to EPs, hospitals, and CAHs that are meaningful users of certified EHR technology. Depending upon when the EP, hospital, or CAH first qualifies as a meaningful user of EHR technology, these incentive payments could begin as early as CY 2011 for EPs, FY 2011 for hospitals, or a cost reporting period beginning during FY 2011 for CAHs. In no case may these incentive payments be made later than CY 2016 for EPs, FY 2016 for hospitals or a cost reporting period beginning after the end of FY 2015 for CAHs.

As we also discussed in the Stage 1 final rule, sections 4101(b) and 4102(b) of the HITECH Act provide as well for reductions in payments to EPs, hospitals, and CAHs that are not meaningful users of certified EHR technology, beginning in CY 2015 for EPs, FY 2015 for hospitals, and in cost reporting periods beginning in FY 2015 for CAHs. We discuss the specific statutory requirements for each of these payment reductions in the following three sections. In these sections, we also present our specific proposals for implementing these mandatory payment reductions.

2. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs Who Are Not Meaningful Users of Certified EHR Technology

Section 1848(a)(7) of the Act, as amended by section 4101(b) of the HITECH Act, provides for payment adjustments effective for CY 2015 and subsequent years for EPs who are not meaningful EHR users during the relevant EHR reporting period for the year. (As defined in § 495.100 of the regulations, for these purposes an EP is a physician, which includes a doctor of medicine or osteopathy, a doctor of dental surgery or medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.) In general, beginning in 2015, if an EP is not a meaningful EHR user for the EHR reporting period for the year, then the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the ''applicable percent'' (defined later) of the fee schedule amount that would otherwise apply. As we also discuss later, the HITECH Act includes an exception, which, if applicable, could exempt certain EPs from this payment adjustment. The payment adjustments do not apply to hospital-based EPs.

The term ''applicable percent'' is defined in the statute to mean: ''(1) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment if the EP is not a successful electronic prescriber in section 1848(a)(5) of the Act for 2014, 98 percent); (2) for 2016, 98 percent; and (3) for 2017 and each subsequent year, 97 percent.''

In addition, section 1848(a)(7)(iii) of the Act provides that if, for CY 2018 and subsequent years, the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case shall the applicable percent be less than 95 percent.

Section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP who is not a meaningful EHR user for the reporting period for the year from the application of the payment adjustment if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient Internet access. The exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years.

a. Applicable Payment Adjustments for EPs Who Are Not Meaningful Users of Certified EHR Technology in CY 2015 and Subsequent Calendar Years

Consistent with these provisions, in the Stage 1 final rule (75 FR 44572), we provided in § 495.102(d)(1) and (2) that, beginning in CY 2015, if an EP is not a meaningful EHR user for an EHR reporting period for the year, then the Medicare PFS amount that would otherwise apply for covered professional services furnished by the EP during the year will be adjusted by the following percentages: for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment for e-prescribing under section 1848(a)(5) of the Act for 2014, 98 percent); (2) for 2016, 98 percent; and (3) for 2017 and each subsequent year, 97 percent.

However, while we discussed the application of the additional adjustment for CY 2018 and subsequent years if the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent in the preamble to the final rule (75 FR 44447), we did not include a specific provision for this adjustment in the regulations text. Therefore, we are proposing to revise the current regulations, to provide specifically that, beginning with CY 2018 and subsequent years, if the Secretary has found that the proportion of EPs who are meaningful EHR users under § 495.8 is less than 75 percent, the applicable percent is decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case is the applicable percent less than 95 percent. We expect to base the determination each year on the most recent CY for which we have sufficient data. The computation would be based on the ratio of EPs who have qualified as meaningful users in the numerator, to Medicare-enrolled EPs in the denominator. We note that the statute requires us to base this determination on ''the proportion of eligible professionals who are meaningful EHR users (as determined under subsection (o)(2).'' Both hospital-based EPs and EPs who have been granted any of the exceptions that we are proposing remain EPs within the statutory definition of the term, as implemented in our regulations in § 495.100 of our regulations. However, hospital-based EPs and EPs granted a exception would not be subject to the determination of meaningful use status ''under subsection (o)(2).'' Therefore, we are proposing to exclude from the denominator of the requisite ratio both the total number of EPs granted an exception in the most recent CY for which we have sufficient data, and all hospital-based EPs from the relevant period. We anticipate that we would compute the requisite ratio of EPs who are meaningful EHR users based on the data available as of October 1, 2017, as this is the last date for EPs to register and attest to meaningful use to avoid a payment adjustment in CY 2018. We would provide more specific detail on this computation in future guidance after the final regulation is published. We note that, in general terms, these two provisions for payment adjustments to EPs who are not meaningful users of EHR technology have the following effects for CY 2015 and subsequent years. The adjustment to the Medicare PFS amount that would otherwise apply for covered professional services furnished by the EP will be 99 percent in CY 2015. However, for CY 2015 the adjustment for an EP who, in CY 2014, was also subject to the application of the payment adjustment for e-prescribing under section 1848(a)(5) of the Act would be 98 percent of the Medicare PFS amount. In CY 2016, the adjustment to the Medicare PFS amount that would otherwise apply will be 98 percent. Similarly, the adjustment to the Medicare PFS amount that would otherwise apply would be 97 percent in CY 2017. Depending on whether the proportion of EPs who are meaningful EHR users is less than 75 percent, the adjustment to the Medicare PFS amount can be as low as 96 percent in CY 2018, and 95 percent in CY 2019 and subsequent years.

It is important to note that some eligible professionals may be eligible for both the Medicare and Medicaid EHR incentives, and have opted for the Medicaid EHR incentive. Under that program, in the first year of their participation, EPs may be eligible for an incentive payment for having adopted, implemented, or upgraded (AIU) to certified EHR technology, as provided in § 495.8(a)(2)(iv). However, AIU does not constitute meaningful use of certified EHR technology. Therefore, those EPs who receive an incentive payment for AIU would not be considered meaningful EHR users for purposes of determining whether EPs are subject to the Medicare payment adjustment. Medicaid EPs who meet the first year requirements through AIU in either 2013 or 2014 will still be subject to the payment adjustment in 2015 if they are not meaningful EHR users for the applicable reporting period. However, Medicaid EPs can, avoid this consequence by making sure that they meet meaningful use in 2013 (or 2014 if this is the first year of participation). Since the Medicaid EHR Incentive Program allows EPs to initiate as late as 2016, AIU can still be an important initial step for providers who missed the window to avoid the Medicare penalties, assuming they then demonstrate meaningful use in the subsequent year.

TABLE 10—PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT THE SECRETARY FINDS THAT LESS THAN 75 PERCENT OF EPS ARE MEANINGFUL EHR USERS FOR CY 2018 AND SUBSEQUENT YEARS

	2015	2016	2017	2018	2019	2020+
EP is not subject to the payment adjustment for e-prescribing in 2014	99	98	97	96	95	95
EP is subject to the payment adjustment for e-prescribing in 2014	98	98	97	96	95	95

TABLE 11—PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT THE SECRETARY ALWAYS FINDS THAT AT LEAST 75 PERCENT OF EPS ARE MEANINGFUL EHR USERS FOR CY 2018 AND SUBSEQUENT YEARS

	2015	2016	2017	2018	2019	2020+
EP is not subject to the payment adjustment for e-prescribing in 2014	99	98	97	97	97	97
EP is subject to the payment adjustment for e-prescribing in 2014	98	98	97	97	97	97

b. EHR Reporting Period for Determining Whether an EP Is Subject to the Payment Adjustment for CY 2015 and Subsequent Calendar Years

In the Stage 1 final rule, we did not specifically discuss the EHR reporting periods that would apply for purposes of determining whether an EP is subject to the payment adjustments for CY 2015 and subsequent years. Section 1848(a)(7)(E)(ii) of the Act provides broad authority for the Secretary to choose the EHR reporting period for this purpose. Specifically, this section provides that ''term 'EHR reporting period' means, with respect to a year, a period (or periods) specified by the Secretary.'' Thus, the statute neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment.

In the case of EPs, we have sought to establish appropriate reporting periods for purposes of the payment adjustments in CY 2015 and subsequent years to avoid creating a situation in which it might be necessary either to recoup overpayments or make additional payments after a determination is made about whether the payment adjustment should apply. This consideration is especially important in the case of EPs because, unlike the case with eligible hospitals and CAHs, there is not an existing mechanism for reconciliation or settlement of final payments subsequent to a payment year, based on the final data for the payment year. (Although, as we discuss in the separate sections later on the payment adjustments for eligible hospitals in CY 2015 and subsequent years, this consideration also carries significant weight even where such a reconciliation or settlement mechanism is available.) Similarly, we do not want to create any scenarios under which providers would be required either to refund money, or to seek additional payment from beneficiaries, due to the need to recalculate beneficiary coinsurance after a determination of whether the payment adjustment should apply. If we were to establish EHR reporting periods that run concurrently with the payment adjustment year, we would not be able to safeguard against such retroactive adjustments (potentially including adjustments to beneficiary copayments, which are determined as a percentage of the Medicare PFS amount).

Therefore, we are proposing that EHR reporting periods for payment adjustments would begin and end prior to the year of the payment adjustment. Furthermore, we are proposing that the EHR reporting periods for purposes of such determinations will be far enough in advance of the payment adjustment year to give us sufficient time to implement the system edits necessary to apply any required adjustments correctly, and that EPs will know in advance of the payment adjustment year whether or not they are subject to the adjustments that we have discussed. Specifically, we believe that the following rules should apply for establishing the appropriate reporting periods for purposes of determining whether EPs are subject to the payment adjustments in CY 2015 and subsequent years:

Except as provided in the second bulleted paragraph, we propose that the EHR reporting period for the 2015 payment adjustment would be the same EHR reporting period that applies in order to receive the incentive for payment year 2013. This proposal would align reporting periods for multiple physician reporting programs. For EPs this would generally be a full calendar year (unless 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period would apply). Under this proposed policy, an EP who receives an incentive for payment year 2013 would be exempt from the payment adjustment in 2015. An EP who received an incentive for payment years in 2011 or 2012 (or both), but who failed to demonstrate meaningful use for 2013 would be subject to a payment adjustment in 2015. (As all of these years will be for Stage 1 of meaningful use, we do not believe that it is necessary to create a special process to accommodate providers that miss the 2013 year for meaningful use). For each year subsequent to CY 2015, the EHR reporting period for the payment adjustment would continue to be the calendar year 2 years prior to the payment adjustment period, subject again to the special exception for new meaningful users of the Certified EHR Technology as follows:

We would create an exception for those EPs who have never successfully attested to meaningful use in the past nor during the regular EHR reporting period we are proposing in the first bulleted paragraph. For these EPs, as it is their first year of demonstrating meaningful use, for the 2015 payment adjustment, we propose to allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months before the end of CY 2014. In addition, the EP would have to actually successfully register for and attest to meaningful use no later than the date that occurs 3 months before the end of CY 2014. For EPs, this means specifically that the latest day the EP must successfully register for the incentive program and attest to meaningful use, and thereby avoid application of the adjustment in CY 2015, is October 1, 2014. Thus, the EP's EHR reporting period must begin no later than July 3, 2014 (allowing the EP a 90-day EHR reporting period, followed by 1 extra day to successfully submit the attestation and any other information necessary to earn an incentive payment). This policy would continue to apply in subsequent years for EPs who are in their first year of demonstrating meaningful use in the year immediately preceding the payment adjustment year.

We believe that these proposed EHR reporting periods provide adequate time both for the systems changes that will be required for us to apply any applicable payment adjustments in CY 2015 and subsequent years, and for EPs to be informed in advance of the payment year whether any adjustment(s) will apply. They also provide appropriate flexibility by allowing more recent adopters of EHR technology a reasonable opportunity to establish their meaningful use of the technology and to avoid application of the payment adjustments. We welcome comments on this proposal.

c. Exception to the Application of the Payment Adjustment to EPs in CY 2015 and Subsequent Calendar Years

As previously discussed, section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustments in CY 2015 and subsequent CYs if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient Internet access. As provided in the statute, the exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. We note that the HITECH Act does not obligate the Secretary to grant exceptions. Nonetheless, we believe that given the timeframes of the HITECH Act payment adjustments there are hardships for which an exception should be granted. We propose three types of exceptions in this proposed rule and are considering a potential fourth. We request public comments on all four exception options. Three types are by definition time limited and should not be at risk of existing for more than 5 years. The

potential fourth refers to barriers facing EPs as discussed further. We believe that these barriers will be lowered over time as internet access, health information exchange and Certified EHR Technology itself becomes available more widely. However, we note that the 5 year limitation is statutory and cannot be altered by regulations.

In the Stage 1 final rule, we provided for this exception in our regulations at § 495.102(d)(3). However, we did not specify the specific circumstances, process, or period for which an exception would be granted. We therefore propose to modify the provision (in a renumbered § 495.102(d)(4)) to specify the circumstances under which an exception would be granted.

First, we propose that the Secretary may grant an exception to EPs who practice in areas without sufficient Internet access. This is in keeping with the language at section 1848(a)(7)(B) of the Act that a significant hardship may exist ''in the case of an eligible professional who practices in a rural area without sufficient Internet access.'' It also recognizes that a non-rural area may also lack sufficient Internet access to make complying with the requirements for being a meaningful EHR user a significant hardship for an EP.

Because exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis, we believe that it is appropriate to require EPs to demonstrate insufficient Internet connectivity to qualify for the exception through an application process. As we have noted, the rationale for this exception is that lack of sufficient Internet connectivity renders compliance with the meaningful EHR use requirements a hardship, particularly for meeting those meaningful use objectives requiring internet connectivity, summary of care documents, electronic prescribing, making health information available online and submission of public health information. Therefore, we believe that the application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives listed previously and insurmountable barriers to obtaining such infrastructure, such as a high cost of extending the Internet infrastructure to their facility. The hardship would be shown for the year that is 2 years prior to the payment adjustment year. We would require applications to be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year.

We are proposing to establish the hardship period 2 years prior to the payment adjustment year because, by definition, the majority of EPs without sufficient Internet connectivity would not have previously been meaningful EHR users. EPs who have never demonstrated meaningful use would generally have a short (90-day) EHR reporting period that occurs in the year before the payment adjustment year. However, if there is insufficient Internet connectivity in the year prior to that reporting period, we believe it is reasonable to assume that the EP would face hardships during the reporting period year, if the EP acquired Internet connectivity and then were required to obtain Certified EHR Technology, implement it, and become a meaningful EHR user all in the same year.

We also encourage EPs to apply for the exception as soon as possible, which would be after the first 90 days (the earliest EHR reporting period) of CY 2013. If applications are submitted close to or on the latest date possible (that is, July 1, 2014 for the 2015 payment adjustment year), then the applications could not be processed in sufficient time to conduct an EHR reporting period in CY 2014 in the event that the application is denied.

Secondly, we propose to provide an exception for new EPs for a limited period of time after the EP has begun practicing. Newly practicing EPs would not be able to demonstrate that they are meaningful EHR users for a reporting period that occurs prior to the payment adjustment year. Therefore, we are proposing that for 2 years after they begin practicing, EPs could receive an exception from the payment adjustments that would otherwise apply in CY 2015 and thereafter. We note that, for purposes of this exception, an EP who switches specialties and begins practicing under a new specialty would not be considered newly practicing. For example, an EP who begins practicing in CY 2015 would receive an exception from the payment adjustments in CYs 2015 and 2016. However, as discussed previously, the new EP would still be required to demonstrate meaningful use in CY 2016 in order to avoid being subject to the payment adjustment in CY 2017. In the absence of demonstrating meaningful use in CY 2016, an EP who had begun practicing in CY 2015 would be subject to the payment adjustment in CY 2017. We will employ an application process for granting this exception, and will provide additional information on the timeline and form of the application in guidance subsequent to the publication of the final rule.

Thirdly, we are proposing an additional exception in this proposed rule for extreme circumstances that make it impossible for an EP to demonstrate meaningful use requirements through no fault of her own during the reporting period. Such circumstances might include: A practice being closed down; a hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require EPs to qualify for the exception through an application process.

We would require applications to be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year. The purpose of this exception is for EPs who would have otherwise be able to become meaningful EHR users and avoid the payment adjustment for a given year. Therefore, it is not necessary to account for circumstances that arise during a payment adjustment year, but rather those that arise in the two years prior to the payment adjustment year (that is in the calendar year immediately prior to the payment adjustment year, or the calendar year that is 2 years prior).

Finally, we are soliciting comments on the appropriateness of granting an exception for EPs meeting certain criteria. These include—

- Lack of face-to-face or telemedicine interaction with patients, thereby making compliance with meaningful use criteria more difficult. Meaningful use requires that a provider is able to transport information online (to a PHR, to another provider, or to a patient) and is significantly easier if the provider has direct contact with the patient and a need for follow up care or contact.

Certain physicians often do not have a consultative interaction with the patient. For example, pathologist and radiologists seldom have direct consultations with patients. Rather, they typically submit reports to other physicians who review the results with their patients;

• Lack of follow up with patients. Again, the meaningful use requirements for transporting information online are significantly easier to meet if a provider immediate contact with or follows up with or contact patients; and

• Lack of control over the availability of Certified EHR Technology at their practice locations.

We do not believe that any one of these barriers taken independently constitutes an insurmountable hardship; however, our experience with Stage 1 of meaningful use suggests that, taken together, they may pose a substantial obstacle to achieving meaningful use. One option is to provide a time-limited, two year payment adjustment exception for all EPs who meet the previous criteria. This approach would allow us to reconsider this issue in future rulemaking. Another option is to provide such an exception with no specific time limit. However, we note that even under this less restrictive option, by statute no individual EP can receive an exception for more than five years. As discussed earlier, we believe the proliferation of both Certified EHR Technology and health information exchange will reduce the barriers faced by specialties with less CEHRT adoption over time as other providers may be providing the necessary data for these specialties to meet meaningful use. We particularly request comment on how soon EPs who meet the previous criteria would reasonably be able to achieve meaningful use.

We believe that EPs who meet the criteria listed previously face unique challenges in trying to successfully achieve meaningful use. However, we encourage comment on whether these criteria, or additional criteria not accounted for in the meaningful use exclusions constitute a significant hardship to meeting meaningful use. For the final rule, we will consider whether to adopt an exception based on these or similar criteria, and, if so, whether such an an exception should apply to individual EPs or across-the-board based on specialty or other groupings that generally meet the appropriate criteria.

The following table summarizes the timeline for EPs to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the penalty:

TABLE 12—TIMELINE FOR ELIGIBLE PROFESSIONALS (OTHER THAN HOSPITAL-BASED) TO AVOID PAYMENT ADJUSTMENT

EP Payment adjustment year (calendar year)	Establish meaningful use for the full calendar year 2 years prior:	OR	For an EP demonstrating meaningful use for the first time in the year prior to the payment adjustment year in a continuous 90-day reporting period beginning no later than:	OR	Apply for an exception no later than:
2015	CY 2013 (with submission period the 2 months following the end of the reporting period).		July 3, 2014 (with submission no later than October 1, 2014).		July 1, 2014.
2016	CY 2014 (with submission period the 2 months following the end of the reporting period).		July 3, 2015 (with submission no later than October 1, 2015).		July 1, 2015.
2017	CY 2015 (with submission period the 2 months following the end of the reporting period).		July 3, 2016 (with submission no later than October 1, 2016).		July 1, 2016.
2018	CY 2016 (with submission period the 2 months following the end of the reporting period).		July 3, 2017 (with submission no later than October 1, 2017).		July 1, 2017.
2019	CY 2017(with submission period the 2 months following the end of the reporting period).		July 3, 2018 (with submission no later than October 1, 2018).		July 1, 2018.

Notes: (CY refers to the calendar year, January 1 through December 31 each year.)
The timelines for CY 2020 and subsequent calendar years will follow the same pattern.

d. Payment Adjustment Not Applicable To Hospital-Based EPs

Section 1848(a)(7)(D) of the Act provides that no EHR payment adjustments otherwise applicable for CY 2015 and subsequent years ''may be made * * * in the case of a hospital-based eligible professional (as defined in subsection (o)(1)(C)(ii)) of the Act.'' We believe the same definition of hospital-based should apply during the incentive and payment adjustment phases of the Medicare EHR incentive program (that is, those eligible to receive incentives would also be subject to adjustments). Therefore, our regulations at § 495.100 and § 495.102(d) would retain, during the payment adjustment phase of the EHR Incentive Program, the definition of hospital-based eligible professional at § 495.4. Section 495.4 defines a hospital-based EP as ''an EP who furnishes 90 percent or more of his or her covered professional services in a hospital setting in the year preceding the payment year. A setting is considered a hospital setting if it is a site of service that would be identified by the codes used in the HIPAA standard transactions as an inpatient hospital, or emergency room setting.'' We further specified in the definition of hospital-based eligible professional that, for purposes of the Medicare EHR incentive payment program, the determination of whether an EP is hospital-based is made on the basis of data from ''the Federal FY prior to the payment year.'' In the preamble to that final rule (75 FR 44442), we also stated that ''in order to provide information regarding the hospital-based status of each EP at the beginning of each payment year, we will need to use claims data from an earlier period. Therefore, we will use claims data from the prior fiscal year (October through September). Under this approach, the hospital-based status of each EP would be reassessed each year, using claims data from the fiscal year preceding the payment year. The hospital-based status will be available for viewing beginning in January of each payment year.'' We will retain the concept established in the stage 1 final rule (75 FR 44442) of making hospital-based determinations

based upon a prior fiscal year of data. However, we are concerned about ensuring that EPs are aware of their hospital-based status in time to purchase EHR technology and meaningfully use it during the EHR reporting period that applies to a payment adjustment year. While EPs who believe that they are not hospital based will have already either worked towards becoming meaningful EHR users or planned for the payment adjustment, EPs who believe that they will be determined hospital based may not have done so. EPs in these circumstances would need to know they are not hospital-based in time to become a meaningful EHR user for a 90-day EHR reporting period in the year prior to the payment adjustment year. To use the example of the CY 2015 payment adjustment year, a determination based on FY 2013 data would allow an EP to know whether he or she is hospital-based by January 1, 2014. This timeline would give the EP approximately 6 months to begin the EHR reporting period, which could last from July through September of 2014. We do not believe this is sufficient time for the EP to implement Certified EHR Technology. Therefore, we are proposing to base the hospital based determination for a payment adjustment year on determinations made 2 years prior. Again using CY 2015 payment adjustment year as an example, the determination would be available on January 1, 2013 based on FY 2012 data. This proposed determination date will give the EP up to 18 months to implement Certified EHR Technology and begin the EHR reporting period to avoid the CY 2015 payment adjustment. We consider this a reasonable time frame to accommodate a difficult situation for some EPs. However, we also are aware that there may be EPs who are determined non-hospital-based under this ''2 years prior'' policy when they would be determined hospital-based if we made the determination just 1 year prior. Again, using the example of the CY 2015 payment adjustment year, an EP determined non-hospital-based as of January 1, 2013 (using FY 2012 data) may be found to be hospital-based as of January 1, 2014 (using FY 2013 data). In this situation, we do not believe the EP should be penalized for having been non-hospital based as of January 1, 2013, especially if the EP has never demonstrated meaningful use, and the EP's first EHR reporting period would have fallen within CY 2014. Therefore, for the final rule, we are considering expanding the hospital-based determination to encompass determinations made either 1 or 2 years prior. Under this alternative, if the EP were determined hospital-based as of either one of those dates, then the EP would be exempt from the payment adjustments in the corresponding payment adjustment year. This would mean that for the CY 2015 payment adjustment year, an EP determined hospital-based as of either January 1, 2013 (using FY 2012 data) or January 1, 2014 (using FY 2013 data) would not be subject to the payment adjustment. In all cases, we would need to know that the EP is considered hospital-based in sufficient time for the payment adjustment year.

3. Incentive Market Basket Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals That Are Not Meaningful EHR Users

In addition to providing for incentive payments for meaningful use of EHRs, section 1886(b)(3)(B)(ix)(I) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to applicable percentage increase to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the associated EHR reporting period for a payment year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, ''for FY 2015 and each subsequent FY,'' an eligible hospital that is not ''a meaningful EHR user * * * for an EHR reporting period'' will receive a reduced update to the IPPS standardized amount. This reduction will apply to ''three-quarters of the percentage increase otherwise applicable.'' The reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user will be ''33⅓ percent for FY 2015, 66⅔ percent for FY 2016, and 100 percent for FY 2017 and each subsequent FY.'' In other words, for eligible hospitals that are not meaningful EHR users, the Secretary is required to reduce the percentage increases otherwise applicable by 25 percent (33⅓ percent of 75 percent) in 2015, 50 (66⅔ percent of 75 percent) percent in FY 2016, and 75 percent (100 percent of 75 percent) in FY 2017 and subsequent years. Section 4102(b)(1)(B) of the HITECH Act also provides that such ''reduction shall apply only with respect to the FY involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase * * * for a subsequent FY.''

TABLE 13—PERCENTAGE DECREASE IN APPLICABLE HOSPITAL PERCENTAGE INCREASE FOR HOSPITALS THAT ARE NOT MEANINGFUL EHR USERS

	2015	2016	2017+
Hospital is subject to EHR payment adjustment	25%	50%	75%

Section 1886(b)(3)(B)(ix)(II) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that the Secretary may, on a case-by-case basis exempt a hospital from the application of the percentage increase adjustment for a fiscal year if the Secretary determines that requiring such hospital to be a meaningful EHR user would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. This section also provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted such an exemption for more than 5 years.

Finally section 1886(b)(3)(B)(ix)(III) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that, for FY 2015 and each subsequent FY, a State in which hospitals are paid for services under section 1814(b)(3) of the Act shall adjust the payments to each eligible hospital in the State that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction in section 1886(b)(3)(B)(ix)(I) of the Act. This section also requires that the State shall report to the Secretary the method it will use to make the required payment adjustment. (At present, section 1814(b)(3) of the Act applies to the State of Maryland.) As we discussed in the Stage 1 final rule establishing the EHR incentive program (75 FR 44448), for purposes of determining whether hospitals are eligible for receiving EHR incentive payments, we employ the CMS Certification Number (CCN). We will also use CCNs to identify hospitals for purposes of determining whether the reduction to the percentage increase otherwise applicable for FY 2015 and subsequent years applies. (In other words, whether a hospital was a meaningful EHR user for the applicable EHR reporting period will be dependent on the CCN for the hospital.). It is important to note the results of this policy for certain cases in which

hospitals change ownership, merge, or otherwise reorganize and the applicable CCN changes. In cases where a single hospital changes ownership, we determine whether to retain the previous CCN or to assign a new CCN depending upon whether the new owner accepts assignment of the provider's prior participation agreement. Where a change of ownership has occurred, and a new CCN is assigned due to the new owner's decision not to accept assignment of the prior provider agreement, we would not recognize a meaningful use determination that was established under the prior CCN for purposes of determining whether the payment adjustment applies. Where the new owner accepts the prior provider agreement and we thus continues to assign the same CCN, we would continue to recognize the demonstration of meaningful use under that CCN. The same policy would apply to merging hospitals that use a single CCN. For example, if hospital A is not a meaningful EHR user (for the applicable reporting period), and it absorbs hospital B, which was a meaningful EHR user, then the entire hospital will be subject to a payment adjustment if hospital A's CCN is the surviving identifier. The converse is true as well—if it were hospital B's CCN that survived, the entire merged hospital would not be subject to a payment adjustment. (The guidelines for determining CCN assignment in the case of merged hospitals are described in the State Operations Manual, sections 2779A ff.) We advise hospitals that are changing ownership, merging, or otherwise reorganizing to take this policy into account.

a. Applicable Market Basket Adjustment for Eligible Hospitals Who Are Not Meaningful EHR Users for FY 2015 and Subsequent FYs

In the stage 1 final rule on the Medicare and Medicaid Electronic Health Record Incentive Payment Programs, we revised § 412.64 of the regulations to provide for an adjustment to the applicable percentage increase update to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015. Specifically, § 412.64(d)(3) now provides that—

Beginning in fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter, three-fourths of the applicable percentage change specified in paragraph (d)(1) of this section is reduced—

(i) For fiscal year 2015, by 33⅓ percent;

(ii) For fiscal year 2016, by 66⅔ percent; and

(iii) For fiscal year 2017 and subsequent fiscal years, by 100 percent.

In order to conform with this new update reduction, as required in section 4102(b)(1)(A) of the HITECH Act, we also revised § 412.64(d)(2)(C) of our regulations to provide that, beginning with FY 2015, the reduction to the IPPS applicable percentage increase for failure to submit data on quality measures to the Secretary shall be one-quarter of the applicable percentage increase, rather than the 2 percentage point reduction that applies for FYs 2007 through 2014 in § 412.64(d)(2)(B). The effect of this revision is that the combined reductions to the applicable percentage increase for EHR use and quality data reporting will not produce an update of less than zero for a hospital in a given FY as long as the hospital applicable percentage increase remains a positive number.

In this proposed rule, we have no further proposals specifically regarding the establishment of the applicable percentage increase adjustment for eligible hospitals who are not meaningful EHR users for FY 2015 and subsequent FYs beyond the provisions we have just cited. However, we believe that the existing regulatory provisions establishing the applicable percentage increase adjustment need to be supplemented to ensure that it is clear that the applicable EHR reporting period, for purposes of determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, will be a prior EHR reporting period (as defined in § 495.4 of the regulations). We have also proposed an amendment to § 412.64(d) to recognize the availability of the exception, as well as the application of the applicable percentage increase adjustment in FY 2015 and subsequent FYs to a State operating under a payment waiver provided by section 1814(b)(3) of the Act. We discuss these issues and present our proposals relating to them in the following sections of this preamble.

b. EHR Reporting Period for Determining Whether a Hospital is Subject to the Market Basket Adjustment for FY 2015 and Subsequent FYs

Section 1886(b)(3)(B)(ix)(IV) of the Act makes clear that the Secretary has discretion to ''specify'' the EHR reporting period that will apply ''with respect to a [calendar or fiscal] year.''

Thus, as in the case of designating the EHR reporting period for purposes of the EP payment adjustment, the statute governing the applicable percentage increase adjustment for hospitals that are not meaningful users of EHR technology neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment.

As in the case of EPs, we wish to avoid creating a situation in which it might be necessary to make large payment adjustments, either to lower or to increase payments to a hospital, after a determination is made about whether the applicable percentage increase adjustment should apply. We believe that this consideration remains compelling in the case of hospitals, despite the fact that the IPPS for acute care hospitals provides, unlike the case of EPs, a mechanism to make appropriate changes to hospital payments for a payment year through the cost reporting process. Despite the availability of the cost reporting process as a mechanism for correcting over- and underpayments made during a payment year, we seek to avoid wherever possible circumstances under which it may be necessary to make large adjustments to the rate-based payments that hospitals receive under the IPPS. As a matter of course in the rate-setting system, the basic rates and applicable percentage increase updates are fixed in advance and are not matters that affect the settlement of final payment amounts under the cost report reconciliation process. Since the EHR payment adjustment in FYs 2015 and subsequent years is an adjustment to the applicable percentage increase, we believe that it is far preferable to determine whether the adjustment applies on the basis of an EHR reporting period before the payment period, rather than to make the adjustment (where necessary) in a settlement process after the payment period on the basis of a determination concerning whether the hospital was a meaningful user during the payment period.

Therefore, we are proposing, for purposes of determining whether the relevant applicable percentage increase adjustment applies to hospitals who are not meaningful users of EHR technology in FY 2015 and subsequent years, that we will establish EHR reporting periods that begin and end prior to the year of the payment adjustment. Furthermore, we are proposing that the EHR reporting periods for purposes of such determinations will be far enough in

advance of the payment year that we have sufficient time to implement the system edits necessary to apply any required applicable percentage increase adjustment correctly, and that hospitals will know in advance of the payment year whether or not they are subject to the applicable percentage increase adjustment. Specifically, we believe that the following rules should apply for establishing the appropriate reporting periods for purposes of determining whether hospitals are subject to the applicable percentage increase adjustment in FY 2015 and subsequent years (parallel to the rules that we proposed previously for determining whether EPs are subject to the payment adjustments in CY 2015 and subsequent years):

• Except as provided in second bulleted paragraph, we propose that the EHR reporting period for the FY 2015 applicable percentage increase adjustment would be the same EHR reporting period that applies in order to receive the incentive for FY 2013. For hospitals this would generally be the full fiscal year (unless FY 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period would apply). Under this proposed policy, a hospital that receives an incentive for FY 2013 would be exempt from the payment adjustment in FY 2015. A hospital that received an incentive for FYs 2011 or 2012 (or both), but that failed to demonstrate meaningful use for FY 2013 would be subject to a payment adjustment in FY 2015. (As all of these years will be for Stage 1 of meaningful use, we do not believe that it is necessary to create a special process to accommodate providers that miss the 2013 year for meaningful use). For each year subsequent to FY 2015, the EHR reporting period payment adjustment would continue to be the FY 2 years before the payment period, subject again to the special provision for new meaningful users of certified EHR technology.

• We would create an exception for those hospitals that have never successfully attested to meaningful use in the past nor during the regular EHR reporting period we are proposing in the first bulleted paragraph previously. For these hospitals, as it is their first year of demonstrating meaningful use, we propose to allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months prior to the end of FY 2014. In addition, the hospital would have to actually successfully register for and attest to meaningful use no later than the date that occurs 3 months before the end of the year. For hospitals, this means specifically that the latest day the hospital must successfully register for the incentive program and attest to meaningful use, and thereby avoid application of the adjustment in FY 2015, is July 1, 2014. Thus, the hospital's EHR reporting period must begin no later than April 3, 2014 (allowing the hospital a 90-day EHR reporting period, followed by one extra day to successfully submit the attestation and any other information necessary to earn an incentive payment). This policy would continue to apply in subsequent years. If a hospital is demonstrating meaningful use for the first time for the fiscal year immediately before the applicable percentage increase adjustment year, then the reporting period would be a continuous 90-day period that begins in such prior fiscal year and ends at least 3 months before the end of such year. In addition all attestation, registration, and any other details necessary to determine whether the hospital is subject to a applicable percentage increase adjustment for the upcoming year would need to be completed by July 1. (As we discuss later, exception requests would be due by the April 1 before the beginning of the next fiscal year.)

In conjunction with adopting these rules for determining the EHR Reporting Period for determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, we are specifically proposing to revise § 412.64(d)(3) of our regulations to insert the phrase ''for the applicable EHR reporting period,'' so that it is clear that the EHR reporting period will not fall within the year of the market basket adjustment.

We believe that these proposed EHR reporting periods provide adequate time both for the systems changes that will be required for CMS to apply any applicable percentage increase adjustments in FY 2015 and subsequent years, and for hospitals to be informed in advance of the payment year whether any adjustment(s) will apply. They also provide appropriate flexibility by allowing more recent adopters of EHR technology a reasonable opportunity to establish their meaningful use of the technology and to avoid application of the payment adjustments. We welcome comments on this proposal.

c. Exception to the Application of the Market Basket Adjustment to Hospitals in FY 2015 and Subsequent FYs

As mentioned previously, section 1886(b)(3)(B)(ix)(II) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that the Secretary may, on a case-by-case basis exempt a hospital from the application of the applicable percentage increase adjustment for a Fiscal year if the Secretary determines that requiring such hospital to be a meaningful EHR user would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. This section also provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted such an exception for more than 5 years.

In this proposed rule we are proposing to add a new§ 412.64(d)(4), specifying the circumstances under which we would exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year. To be considered for an exception, a hospital must submit an application demonstrating that it meets one or both of the following criteria.

As noted previously, the statute does not mandate the circumstances under which an exception must be granted, but (as in the case of a similar exception provided under the statute for EPs) it does state that the exception may be granted when ''requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.'' We are therefore proposing to provide in new § 412.64(d)(4) that the Secretary may grant an exception to a hospital that is located in an area without sufficient Internet access. Furthermore, while the statute specifically states that such an exception may be granted to hospitals in ''a rural area without sufficient Internet access,'' it does not require that such an exception be restricted only to rural areas without such access. While we believe that a lack of sufficient Internet access will rarely be an issue in an urban or suburban area, we do not believe that it is necessary to preclude the possibility that, in very rare and exceptional cases, a non-rural area may also lack sufficient Internet access to make complying with meaningful use requirements a significant hardship for a hospital. Therefore, we are providing that the Secretary may grant such an exception to a hospital in any area without sufficient Internet access.

Because exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis, we believe that it is appropriate to require hospitals to demonstrate insufficient Internet connectivity to qualify for the exception through an application process. The

rationale for this exception is that lack of sufficient Internet connectivity renders compliance with the meaningful EHR use requirements a hardship particularly those objectives requiring internet connectivity, summary of care documents, electronic prescribing, making health information available online and submission of public health information. Therefore, we believe that such an application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives listed previously and insurmountable barriers to obtaining such internet connectivity such as high cost to build out Internet to their facility. As with EPs, the hardship would be demonstrated for period that is 2 years prior to the payment adjustment year (for example, FY 2013 for the payment adjustment in FY 2015). As with EPs, we would require applications to be submitted 6 months before the beginning of the payment adjustment year (that is, by April 1 before the FY to which the adjustment would apply) in order to provide sufficient time for a determination to be made and for the hospital to be notified about whether an exception has been granted. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to hospitals who have received an exception for a specific FY. (Please also see our previous discussion of the parallel exception for EPs, with respect to encouraging providers to file these applications as early as possible, and the likelihood that there will not be an opportunity to subsequently demonstrate meaningful use if hospitals file close to or at the application deadline of April 1.)

For the same reasons we are proposing an exception for new EPs, we propose an exception for a new hospital for a limited period of time after it has begun services. We would allow new hospitals an exception for at least 1 full year cost reporting period after they accept their first patient. For example, a hospital that accepted its first patient in March of 2015, but with a cost reporting period from July 1 through June 30, would receive an exception from payment adjustment for FY 2015, as well as for FY 2016. However, the new hospital would be required to demonstrate meaningful use within the 9 months of FY 2016 (register and attest by July 1, 2016) to avoid being subject to the payment adjustment in FY 2017.

In proposing such an exception for new hospitals, however, it is important to ensure that the exception is not available to hospitals that have already been in operation in one form or another, perhaps under a different owner or merely in a different location, and thus have in fact had an opportunity to demonstrate meaningful use of EHR technology. Therefore, for purposes of qualifying for this exception, the following hospitals would not be considered new hospitals exception:

- A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.
- A hospital that closes and subsequently reopens.
- A hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.
- A hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital in patient prospective payment systems.

It is important to note that we would consider a hospital that changes its status from a hospital (other than a CAH) that is excluded from the Medicare hospital inpatient prospective payment system (IPPS) to a hospital that is subject to the IPPS to be a new hospital for purposes of qualifying for this proposed exception. These IPPS-exempt hospitals, such as long-term care hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities children's hospitals, and cancer hospitals, are excluded from the definition of ''eligible hospital'' for purposes of the Medicare EHR Incentive Program and have not necessarily had an opportunity to demonstrate meaningful use. On the other hand, CAHs are eligible for incentive payments and subject to payment adjustments. Under the guidelines for assigning CCNs to Medicare providers, a CAH that changes status to an IPPS hospital would necessarily receive a new CCN. This is because several digits of the CCN encode the provider's status (for example, IPPS, CAH) under the Medicare program. However, we would allow the CAH to register its meaningful use designation obtained under its previous CCN in order to avoid being subject the hospital payment adjustment. It is worth noting that we have adapted the proposed definition of ''new hospital'' for these purposes from similar rules that have been employed in the capital prospective payment system in § 412.300(b) of our regulations. We welcome comment concerning the appropriateness of adapting these rules to the exception under the EHR program, and about whether modifications or other revisions to these rules would be appropriate in the EHR context.

Finally, we are proposing an additional exception in this proposed rule for extreme circumstances that make it impossible for a hospital to demonstrate meaningful use requirements through no fault of its own during the reporting period. Such circumstances might include: a hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require hospitals to qualify for the exception through an application process.

We would require applications to be submitted no later than April 1 of the year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the hospital to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to hospitals who have received an exception for a specific payment adjustment year. The purpose of this exception is for hospitals who would have otherwise be able to become meaningful EHR users and avoid the payment adjustment for a given year. Therefore, it is not necessary to account for circumstances that arise during a payment adjustment year, but rather those that arise in the 2 years prior to the payment adjustment year.

The following table summarizes the timeline for hospitals to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the adjustment.

TABLE 14—TIMELINE FOR ELIGIBLE HOSPITALS TO AVOID PAYMENT ADJUSTMENT

Hospital payment adjustment year (fiscal year)	Establish meaningful use the full fiscal year 2 years prior:	OR	For an eligible hospital demonstrating meaningful use for the first time in the year prior to the payment adjustment year use a continuous 90-day reporting period beginning no later than:	OR	Apply for an exception no later than:
2015	FY 2013 (with submission period the 2 months following the end of the reporting period).		April 3, 2014 (with submission no later than July 1, 2014).		April 1, 2014.
2016	FY 2014 (with submission period the 2 months following the end of the reporting period).		April 3, 2015 (with submission no later than July 1, 2015).		April 1, 2015.
2017	FY 2015 (with submission period the 2 months following the end of the reporting period).		April 3, 2016 (with submission no later than July 1, 2016).		April 1, 2016.
2018	FY 2016 (with submission period the 2 months following the end of the reporting period).		April 3, 2017 (with submission no later than July 1, 2017).		April 1, 2017.
2019	FY 2017 (with submission period the 2 months following the end of the reporting period).		April 3, 2018 (with submission no later than July 1, 2014).		April 1, 2018.

Notes: (FY refers to the Federal fiscal year: October 1 to September 30. For example, FY 2015 is October 1, 2014 through September 30, 2015.)

The timelines for FY 2020 and subsequent fiscal years follow the same pattern.

d. Application of Market Basket Adjustment in FY 2015 and Subsequent FYs to a State Operating Under a Payment Waiver Provided by Section 1814(b)(3) of the Act

As discussed previously, the statute requires payment adjustments for eligible hospitals in States where hospitals are paid under section 1814(b)(3) of the Act. Such adjustments shall be designed to result in an aggregate reduction in payments equivalent to the aggregate reduction that would have occurred if payments had been reduced under section 1886(b)(3)(B)(ix)(I) of the Act. In this context, we would consider that an aggregate reduction in payments would mean the same dollar amount in reduced Medicare payments that that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction under § 412.64(d)(3).

To implement this provision, we propose a new § 412.64(d)(5) that includes this statutory requirement. States operating under a payment waiver under section 1814(b)(3) of the Act must provide to the Secretary, no later than January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment.

In this context, we are also proposing that an aggregate reduction in payments would mean the same dollar amount in reduced Medicare payments that that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction under § 412.64(d)(3).

4. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

Section 4102(b)(2) of the HITECH Act amends section 1814(l) of the Act to include an adjustment to a CAH's Medicare reimbursement for inpatient services if the CAH has not met the meaningful EHR user definition for an EHR reporting period. The adjustment would be made for a cost reporting period that begins in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act now provide that, if a CAH has not demonstrated meaningful use of certified EHR technology for an applicable reporting period, then for a cost reporting period that begins in FY 2015, its reimbursement would be reduced from 101 percent of its reasonable costs to 100.66 percent. For a cost reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent FY, its reimbursement would be reduced to 100 percent of reasonable costs.

However, as provided for eligible hospitals, a CAH may, on a case-by-case basis, be granted an exception from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that a significant hardship exists, such as in the case of a CAH in a rural area without sufficient Internet access. However, in no case may a CAH be granted an exception under this provision for more than 5 years.

a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

In the stage 1 final rule (75 FR 44564), we finalized the regulations regarding the CAH adjustment at § 495.106(e) and § 413.70(a)(6).

b. EHR Reporting Period for Determining Whether a CAH is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years

For CAHs we propose an EHR reporting period that is aligned with the payment adjustment year. For example, if a CAH is not a meaningful EHR user in FY 2015, then its Medicare reimbursement will be reduced to 100.66 for its cost reporting period that begins in FY 2015. This differs from what is being proposed for eligible hospitals where the EHR reporting period will be prior to the market basket adjustment year. We believe the Medicare cost report process would allow us to make the CAH reduction for the cost reporting period that begins in the payment adjustment year, with minimal disruptions to the CAH's cash flow and minimal administrative burden on the Medicare contractors as discussed later.

CAHs are required to file an annual Medicare cost report that is typically for a consecutive 12-month period. The cost report reflects the inpatient statistical and financial data that forms the basis

of the CAH's Medicare reimbursement. Interim Medicare payments may be made to the CAH during the cost reporting period based on the previous year's data. Cost reports are filed with the CAH's Medicare contractor after the close of the cost reporting period and the data on the cost report are subject to reconciliation and a settlement process prior to a final Medicare payment being made.

We have proposed an amended definition of the EHR reporting period that will apply for purposes of payment adjustments under § 495.4. For CAHs this will be the full Federal fiscal year that is the same as the payment adjustment year (unless a CAH is in its first year of demonstrating meaningful use, in which case a continuous 90-day reporting period within the payment adjustment year would apply). The adjustment would then apply based upon the cost reporting period that begins in the payment adjustment year (that is, FY 2015 and thereafter). Thus, if a CAH is not a meaningful user for FY 2015, and thereafter, then the adjustment would be applied to the CAH's reasonable costs incurred in a cost reporting period that begins in that affected FY as described in § 413.70(a)(6)(i).

CAHs are required to submit their attestations on meaningful use by November 30th of the following FY. For example, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than November 30, 2015. Such an attestation (or lack thereof) would then affect interim payments to the CAH made after December 1st of the applicable FY. If the cost reporting period ends prior to December 1st of the applicable FY then any applicable payment adjustment will be made through the cost report settlement process.

c. Exception to the Application of Reasonable Cost Payment Reductions to CAHs in FY 2015 and Subsequent FYs

As discussed previously, CAHs may receive exceptions from the payment adjustments for significant hardship. While our current regulations, in § 413.70(a)(6)(ii) and (iii) contain this hardship provision we are proposing to revise these regulations to align them with the exceptions being proposed for EPs and subsection (d) hospitals. As with EPs and subsection (d) hospitals CAHs could apply for an exception on the basis of lack of sufficient Internet connectivity. Applications would be required to demonstrate insufficient Internet connectivity to comply with the meaningful use objectives requiring internet connectivity (that is, summary of care documents, electronic prescribing, making health information available online and submission of public health information) and insurmountable barriers to obtaining such internet connectivity. As CAHS will have an EHR reporting period aligned with the payment adjustment year, the insufficient Internet connectivity would need to be demonstrated for each applicable payment adjustment year. For example, to avoid a payment adjustment for cost reporting periods that begin during FY 2015, the hardship would need to be demonstrated for FY 2015. For each year subsequent to FY 2015, the basis for an exception would continue to be for the hardship in the FY in which the affected cost reporting period begins. As stated in § 413.70(a)(6)(iii), any exception granted may not exceed 5 years. After 5 years, the exception will expire and the appropriate adjustment will apply if the CAH has not become a meaningful EHR user.

As with new EPs and new eligible hospitals, we are also proposing an exception for a new CAH for a limited period of time after it has begun services. We would allow an exception for 1 year after they accept their first patient. For example, a CAH that is established in FY 2015 would be exempt from the penalty through its cost reporting period ending at least one year after the CAH accepts its first patient. If the CAH is established March 15 of 2015 and its first cost reporting period is less than 12 months (for example, from March 15 through June 30, 2015), the exception would exist for both the short cost reporting period and the following 12-month cost reporting period lasting from July 1, 2015 through June 30, 2016. However, the new CAH would be required to submit its attestation that it was a meaningful EHR user for FY 2016 no later than November 30 of 2016, in order to avoid being subject to the payment adjustment for the cost reporting period that begins in FY 2016 (in the previous example from July 1, 2016 through June 30, 2017).

In proposing such an exception for newly established CAHs, it is important to ensure that the exception is not available to CAHs that have already been in operation in one form or another, perhaps under a different ownership or merely in a different location, and thus have in fact had an opportunity to demonstrate meaningful use of EHR technology. Therefore, for the purposes of qualifying for this exception, a new CAH means a CAH that has operated (under previous or present ownership) for less than 1 year.

In some cases an eligible hospital may convert to a CAH. An eligible hospital is a subsection (d) hospital that is a meaningful user and is paid under the inpatient hospital prospective payment systems as described in subpart A of Part 412 of the regulations. In these cases, eligible hospitals were able to qualify for purposes of the EHR hospital incentive payments by establishing meaningful use, and (as discussed previously) are also subject to a payment penalty provision in FY 2015 and subsequent years if they fail to demonstrate meaningful use of EHR technology during an applicable reporting period. Therefore, we are proposing not to treat a CAH that has converted from an eligible hospital as a newly established CAH for the purposes of this exception.

On the other hand, other types of hospitals such as long-term care hospitals, psychiatric hospitals, and inpatient rehabilitation facilities are not subsection (d) hospitals. These other types of hospitals do not meet the definition of an ''eligible hospital'' for purposes of the Medicare EHR hospital incentive payments and the application of the proposed hospital market basket adjustment in FY 2015 and subsequent years under section 1886(n)(6)(B) of the Act. In some instances, a CAH may be converted from one of these types of hospitals. In that case, the CAH would not have had an opportunity to demonstrate meaningful use, and it is therefore appropriate to treat them as newly established CAHs if they convert from one of these other types of hospitals to a CAH for purposes of determining whether they should qualify for an exception from the application of the adjustment in FY 2015 and subsequent years. Thus, we are proposing to consider a CAH that converts from one of these other types of hospitals to be a newly established CAH for the purposes of qualifying for this proposed exception from the application of the adjustment in FY 2015 and subsequent years.

In summary, we propose for purposes of qualifying for the exception to revise § 413.70(a)(6)(ii) to state that a newly established CAH means a CAH that has operated (under previous or present ownership) for less than 1 year. We also propose to revise § 413.70(a)(6)(ii) to state that the following CAHs are not newly established CAHs for purposes of this exception:

- A CAH that builds new or replacement facilities at the same or another location even if coincidental

with a change of ownership, a change in management, or a lease arrangement.

- A CAH that closes and subsequently reopens.
- A CAH that has been in operation for more than 1 year but has participated in the Medicare program for less than 1 year.
- A CAH that has been converted from an eligible subsection (d) hospital.

Finally, we are proposing an additional exception in this proposed rule for extreme circumstances that make it impossible for a CAH to demonstrate meaningful use requirements through no fault of its own during the reporting period. Such circumstances might include: a CAH is closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require CAHs to qualify for the exception through an application process.

As described previously, we are proposing to align a CAH's payment adjustment year with the applicable EHR reporting period. A CAH must submit their meaningful use attestation for a specific EHR reporting period no later than 60 days after the close of that EHR reporting period (or November 30th of the subsequent EHR reporting period) otherwise the payment penalty could be applied to the CAH's cost reporting period that begins in that payment adjustment year. We are proposing to require a CAH to submit an application for an exception, as described previously, to its Medicare contractor by the same November 30th date that the meaningful use attestation is due. Therefore, a CAH will be subject to the payment penalty if it has not submitted its meaningful use attestation (or its attestation has been denied) and has not submitted an application for an exception by November 30th of the subsequent EHR reporting period. If a CAH's request for an exception is not granted by the Medicare contractor then the payment penalty will be applied. If a CAH anticipates submitting an exception application we recommend that the CAH communicate with its Medicare contractor to determine the necessary supporting documentation to submit by the November 30th due date.

Table 15, summarizes the timeline for CAHs to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the adjustment.

TABLE 15—TIMELINE FOR CAHS TO AVOID PAYMENT ADJUSTMENT

CAH with cost reporting period beginning during payment adjustment year:	Establish meaningful use for the EHR reporting period:	OR	For a CAH demonstrating meaningful use for the first time, a continuous 90-day reporting period ending no later than:	OR	Apply for an exception no later than:
FY 2015	FY 2015 (with submission no later than November 30, 2015).		September 30, 2015 (with submission no later than November 30, 2015).		November 30, 2015.
FY 2016	FY 2016 (with submission no later than November 30, 2016).		September 30, 2016 (with submission no later than November 30, 2016).		November 30, 2016.
FY 2017	FY 2017 (with submission no later than November 30, 2017).		September 30, 2017 (with submission no later than November 30, 2017).		November 30, 2017.
FY 2018	FY 2018 (with submission no later than November 30, 2018).		September 30, 2018 (with submission no later than November 30, 2018).		November 30, 2018.
FY 2019	FY 2019 (with submission no later than November 30, 2019).		September 30, 2019 (with submission no later than November 30, 2019).		November 30, 2019.

Notes: (FY refers to the Federal fiscal year: October 1 to September 30. For example, FY 2015 is October 1, 2014 to September 30, 2015.) The timelines for FY 2020 and subsequent fiscal years follow the same pattern.

5. Proposed Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

The Stage 1 final rule established requirements in 42 CFR 495.370 for States to create appeals processes under the Medicaid EHR Incentive Program, but did not establish an appeal process for all of the EHR Incentive Program. In § 495.404, we are proposing a process for Medicare EPs, eligible hospitals, CAHs, qualifying MA organizations on behalf of an EP, and qualifying MA-affiliated hospitals in a limited circumstance to file an appeal in the Medicare FFS EHR Incentive Program. (See proposed § 495.213 of the regulations text for a discussion of the appeal process proposed for the MA EHR Incentive Program). In § 495.404(f), we are proposing an appeal process for Medicaid providers in a limited circumstance, specifically when we conduct a meaningful use audit of the Medicaid eligible hospital and make an adverse audit finding.

Although the HITECH Act prohibits both administrative and judicial review of the standards and method used to determine eligibility and payment (including those governing meaningful use) (see 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212), we believe a limited appeal process is warranted in certain cases involving individual applicability; that is, where a provider, as defined in § 495.400, is challenging not the standards and methods themselves, but whether the provider met the regulatory standards and methods promulgated by CMS in its rules.

The proposed administrative appeals process applies to both Stage 1 and Stage 2 of meaningful use. We will post guidance on the CMS Web site, *http://www.cms.gov/qualitymeasures/05_ehrincentiveprogramappeals.asp,* in the interim between the publication of this proposed rule and the publication of the final rule. We seek public comments both on the guidance and the proposed rule.

We note that in all cases, we would require that requests for appeals, all filings, and all supporting documentation and data be submitted through an online mechanism in a manner specified by CMS.

a. Permissible Appeals

We propose to limit permissible appeals to the following three types of appeals:

(1) Eligibility Appeals

These appeals could be filed by EPs, eligible hospitals, or CAHs. The provider would need to demonstrate that it meets all the EHR Incentive Program requirements except for the issue raised and should have received a payment but could not because of a circumstance outside the provider's control. A circumstance outside a provider's control is any event, as defined by us, which reasonably prevented a provider from participating in the EHR Incentive Program, and which the provider could not under any circumstance control. For example, system issues wholly within the control of CMS that could not be resolved to allow a provider to participate in the EHR Incentive Program or natural disasters that prevent the provider from registering or attesting might be circumstances outside the control of the provider, depending upon the specific situation.

In limited circumstances, an MA-affiliated eligible hospital could also file an eligibility appeal based on common corporate governance with a qualifying MA organization, for which at least two thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans or whether it meets the requirement of section 1853(m)(3)(B)(i) of the Act to be an MA-affiliated hospital because it has less than one-third of Medicare bed-days covered under Part A rather than Part C.

(2) Meaningful Use Appeals

These appeals could be filed by EPs, eligible hospitals, CAHs, and MA organizations on behalf of MA providers to challenge adverse audit or other findings that the provider did not, in fact, demonstrate that it is a meaningful EHR user, or, that it did not demonstrate it was using certified EHR technology. (See section II.F. of this proposed rule, explaining proposed amendments to § 495.316 and § 495.332). These appeals could be filed by Medicaid providers in a limited circumstance, specifically when we conduct a meaningful use audit of the Medicaid eligible hospital and make an adverse audit finding. States would agree in their State Medicaid Health Information Technology Plans (SMHPs) to be bound by our audit and appeal determinations on meaningful use). Medicaid EPs would continue to use the State appeal process for all appeals under the Medicaid EHR Incentive Program.

(3) Incentive Payment Appeals

These appeals could be filed by Medicare EPs. The appeal would need to challenge the claims count used at attestation for determining the incentive payment. The appeal could not contest an individual claims payment or coverage decisions, but only the inclusion of final claims used to calculate the incentive payment amount. The appeal could also challenge a recoupment of an incorrect incentive payment based on any Federal determination (including a recoupment based on duplicative payment). Any issue involving incentive payment based upon a hospital cost report must be filed with the Provider Reimbursement and Review Board (PRRB); thus appeals raising hospital cost report issues will be dismissed in accordance with these proposed rules. However, we wish to make clear that the PRRB would not have jurisdiction over issues to be decided under the administrative process described in this proposal (for example, eligibility issues or whether a provider was a meaningful EHR user).

b. Filing Requirements

(1) Filing Deadlines

Appeals filed by a provider after the specified deadline would be dismissed and could not be re-filed, except under extenuating circumstances. If the filing deadline falls on a Saturday, Sunday, or a Federal holiday, then, the filing deadline would be extended to the next business day. We propose the following filing deadlines for each appeal:

- An eligibility appeal must be filed no later than 30 days after the 2-month period following the payment year.
- A meaningful use appeal must be filed no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive payment.
- An incentive payment appeal must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any Federal determination that the incentive payment calculation was incorrect (including determinations that payments were duplicative).

A provider could request to extend the filing deadline by showing extenuating circumstances existed, which prevented the provider from filing the appeal by the applicable deadline. To demonstrate extenuating circumstances, a provider would need to present documentation (in its late filing) that occurrences, events, or transactions prevented the provider from filing by the applicable deadline. Extenuating circumstances will be decided on a case-by-case basis. Extenuating circumstances include, but are not limited to, system issues that affect a provider's incentive payment. We may extend the filing deadline for providers in response to extenuating circumstances that occur within the EHR Incentive Program. We will provide information on our Web site at least 7 calendar days before the filing deadline providing the new filing deadline.

A provider could withdraw an appeal at any time after the initial appeal filing and before an informal review decision is issued. The issues raised in the appeal filing could be refiled by the provider if prior to the specified filing deadline as specified in § 495.408(b).

(2) Issues Raised at Time of Filing

A provider would be required to raise all relevant issues at the time of the initial filing of an appeal. Except under extenuating circumstances, issues not raised at the initial appeal filing could not be raised at a later time and would be dismissed. To demonstrate extenuating circumstances, a provider would need to show (in its amendment filing) that circumstances beyond the provider's control prevented all relevant issues from being included at the time of the initial appeal filing. For example, the provider received documentation from another entity after the initial appeal filing, which raised additional issues that should have been included in the initial appeal filing. The provider would be required to provide (with its amendment filing) documentation of occurrences, events, or transactions that prevented the additional issues from being raised at the initial appeal filing. We propose that any amendment must be filed no later than 15 days after the initial appeal filing deadline.

c. Preclusion of Administrative and Judicial Review

Any provider using our administrative appeal process would have the burden of showing at the time of the initial appeal filing that any issue raised in the appeal is not precluded from administrative and judicial review under the HITECH Act and our regulations at 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212. Appeal issues found to be precluded would be dismissed.

d. Inchoate Review

We propose that issues raised in an appeal would also be reviewed for

premature or inchoate issues. Issues are considered inchoate or premature if a provider is challenging a program issue that we still have an opportunity to resolve before the end of the respective payment period as indicated in the filing deadlines. The provider would have the burden of demonstrating in the initial appeal filing that the provider allowed us an opportunity to resolve the issue, and provide documentation of such resolution efforts (for example, documentation from contacting the EHR Information Center and demonstrating the issue was still not resolved or a demand letter has been issued asking for recoupment of an incentive payment.) A provider that is unable to meet the burden would have their appeal dismissed and have the opportunity to refile when the provider can demonstrate: (1) That it has met all the program requirements other than the issue raised and should have received an incentive payment; (2) CMS was not able to resolve the issue before the end of the payment year; and (3) the appeal challenges the same program issues from the dismissed inchoate or premature appeal and is filed no later than 30 days after the 2-month period following the payment year for which the initial appeal was filed.

e. Informal Review Process Standards

Properly filed appeals (using the filing rules discussed previously) would first be subject to informal review, in accordance with the following process and standards: For eligibility appeals, the provider would be required to demonstrate at the initial appeal filing that it meets all of the requirements of the EHR Incentive Program except for the issue raised, that the issue raised was the result of a circumstance outside of the provider's control that prevented the provider from receiving an incentive payment, and submit evidence that the provider took action to participate in the EHR Incentive Program. We are also proposing special rules for MA-affiliated hospitals appealing determinations regarding common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans or that the hospital has less than one-third of Medicare bed-days for the year covered under Part A rather than Part C.

For meaningful use appeals, the provider would be required to demonstrate that it met the meaningful use objectives and associated measures discussed in the demand letter issued by CMS or other findings that could result in a recoupment of the EHR incentive payment and that the provider used certified EHR technology during the EHR reporting period for the payment year for which the appeal was filed.

For incentive payment appeals, the provider would be required to demonstrate that all relevant claims were submitted timely, according to the requirements set forth in the EHR Incentive Program but that the timely and appropriately filed claims were not included in calculating the amount of the EHR incentive payment. The EHR Incentive Program requires all claims be filed no later than 2 months after the end of the payment year. Nevertheless, we believe there may be situations in which timely filed claims are not reflected in our integrated data repository (IDR) due to claims processing delays. In this case, we will nevertheless calculate incentive payments based on the allowed charges for covered professional services included in the IDR (by our deadline for making incentive payments). However, EPs will be able to file appeals of these payment amounts, if they can show that timely filed claims were not included in the calculation, and that they would have received a higher incentive payment had such claims been included. We believe that at the time such appeals are filed, the IDR will have more up-to-date information, thereby allowing us to determine these appeals based on the allowed charges for the timely filed claims.

f. Request for Supporting Documentation—Documentation Essential To Validate an Issue Raised in the Appeal

We propose that providers would have 7 calendar days to comply with the request for supporting documentation. Missing this 7-day deadline would result in dismissal of the appeal, except in extenuating circumstances. A provider would be required to demonstrate that extenuating circumstance existed that prevented the provider from submitting supporting documentation within the required 7-day deadline. Extenuating circumstances would be decided on a case-by-case basis, for example, if a provider received documentation from another entity after the 7 calendar days to respond to the request for supporting documentation.

g. Informal Review Decision

We propose that an informal review decision would be rendered within 90 days after the initial appeal filing, unless extensions or amendments are granted.

h. Final Reconsideration

We propose that providers dissatisfied with an informal review decision could file a request for reconsideration of issues denied in the informal review decision. All comments and documentation supporting the provider's position that the issues denied in the appeal should have been approved would be required to be submitted within 15 days from the date of the informal review decision. Requests for reconsideration would be reviewed with the same standards of review as the informal review. One-time extensions of 15 additional days could be requested, if the provider could demonstrate that it did not receive the informal review decision within 5 days of the date on the informal review decision.

We would render a final decision on the request for reconsideration within 10 days after the request for reconsideration and all supporting documentation and data are received.

If the provider does not request reconsideration, the informal review decision is a final decision by CMS.

i. Exhaustion of Administrative Review

We expect all providers to exhaust the administrative review process proposed in this rule, prior to seeking review in Federal Court.

E. Medicare Advantage Organization Incentive Payments

1. Definitions (§ 495.200)

We propose to add definitions of the terms ''Adverse eligibility determination,'' ''Adverse payment determination'' and ''MA payment adjustment year.'' Please see the discussion in section II.E.5 of this proposed rule. We also would add a definition for the term ''Potentially qualifying MA–EPs and potentially qualifying MA-affiliated eligible hospitals,'' to cross reference the existing definition at § 495.202(a)(4).

We propose to clarify the application of ''hospital-based EP'' as that term is used in paragraph 5 of the definition of qualifying MA EP in § 495.200, to make clear that the calculation is not based on FFS covered professional services, but rather on MA plan enrollees. Otherwise, qualifying MA EPs who provide at least 80 percent of their covered professional services to MA plan enrollees of qualifying MA organizations might be considered ''hospital based'' solely on the basis of the fact that 90 percent of their FFS covered professional services

were provided in a hospital setting. For example, a qualifying MA EP might bill FFS 10 times over a year because of emergency room services provided to various patients. Although the vast majority of the MA EP's covered services were reimbursed under his or her arrangement with the MA organization, 100 percent (or 10) of the MA EP's FFS covered services would be for hospital-based services, which would otherwise prohibit the MA organization from receiving reimbursement under the MA EHR incentive program for the MA EP. We do not believe we should exclude MA EPs from the MA EHR Incentive Program due to only a few FFS claims. In addition, MA organizations may not have access to an MA EP's FFS covered professional service data if the professional services were rendered outside of the employment arrangement between the qualifying MA organization and the qualifying MA EP. Therefore, we are clarifying in the definition of ''qualifying MA EP'' that for purposes of the MA EHR Incentive Program, a hospital-based MA EP provides 90 percent or more of his or her covered professional services in a hospital setting to MA plan enrollees of the qualifying MA organization.

2. Identification of Qualifying MA Organizations, MA-EPs and MA-Affiliated Eligible Hospitals (§ 495.202)

We propose a technical change to § 495.202(b)(1) to indicate that the qualifying MA organizations must identify those MA EPs and MA-affiliated eligible hospitals that the qualifying MA organization believes will be meaningful users of certified EHR technology during the reporting period, if a qualifying MA organization intends to claim an incentive payment for a given qualifying MA EP or MA-affiliated eligible hospital.

In § 495.202(b)(2), we clarify that qualifying MA organizations must report the CMS Certification Number (CCN) for qualifying MA-affiliated eligible hospitals. As this program matures, this is a detail that became necessary to report in order to properly administer the program.

We propose a new § 495.202(b)(3) to include a reporting requirement to ensure that we can identify which qualifying MA EPs a given qualifying MA organization believes have furnished more than 50 percent of his or her covered Medicare professional services to MA enrollees of the qualifying MA organization in a designated geographic Health Professional Shortage Area (HPSA) during the reporting period. We also propose to redesignate the current § 495.202(b)(3) as (b)(4), and revise the introductory language in (b)(2) to reflect this redesignation.

We require in the current § 495.202(b)(3) that MA organizations identify qualifying MA EPs or MA-affiliated eligible hospitals within 60 days of the close of the payment year. We are proposing to change the 60-day requirement to a 2-month requirement in order to be more consistent with the Medicare FFS EHR Incentive Program. In nonleap years this would reduce the time for reporting revenue amounts to CMS for qualifying MA EPs from 60 days to 59 days. We are proposing conforming amendments to § 495.204(b)(2) and § 495.210(b) and (c).

Because the redesignated § 495.202 (b)(4) relates to both the payment phase and the payment adjustment phase of the program, we added the word ''qualifying'' to the text of the regulation. Therefore this regulation applies to both qualifying MA EPs and MA-affiliated eligible hospitals (payment and payment adjustment phases) and potentially qualifying MA EPs and MA-affiliated eligible hospitals (payment adjustment phase) of the program.

We redesignated the current § 495.202(b)(4) as § 495.202(b)(5), and indicated that the qualifying MA organization must identify the MA EPs and MA-affiliated eligible hospitals that it believes will be both ''qualifying'' and ''potentially qualifying.'' In order to calculate the payment adjustment, we will need to know how many qualifying MA EPs and MA-affiliated eligible hospitals are and are not meaningful users. We also propose to correct a cross-reference.

3. Incentive Payments to Qualifying MA Organizations for Qualifying MA EPs and Qualifying MA-Affiliated Eligible Hospitals (§ 495.204)

a. Amount Payable to a Qualifying MA Organization for Its Qualifying MA EPs

In § 495.204(b), we propose to clarify that methods relating to overhead costs may be submitted for MA EPs regardless of whether the MA EP is salaried or paid in another fashion, such as on a capitated basis, where appropriate.

As stated previously, we also propose to require MA organizations, to submit revenue amounts relating to their qualifying MA EPs within 2 months of the close of the calendar year, as opposed to 60 days.

b. Increase in Incentive Payment for MA EPs Who Predominantly Furnish Services in a Geographic Health Professional Shortage Area (HPSA)

In a new § 495.204(e) (the current paragraph (e) would be redesignated paragraph (f)), we propose to add a provision governing whether a qualifying MA organization is entitled to a HPSA increase for a given qualifying MA EP. Section 1848(o)(1)(B)(iv) of the Act, which is currently in effect, and as applied to the MA program, provides a 10-percent increase in the maximum incentive payment available if the MA EP predominantly furnishes his or her covered professional services during the MA EHR payment year in a geographic HPSA. Consistent with the Medicare FFS EHR Incentive Program, we interpret the term ''predominantly'' to mean more than 50 percent. For the MA EHR Incentive Program, we propose to determine eligibility for the geographic HPSA increase on whether the qualifying MA EP predominantly provided services to MA plan enrollees of the qualifying MA organization in a HPSA during the applicable MA EHR payment year.

It is worth noting that an MA organization does not automatically receive a HPSA bonus merely because its qualifying MA EPs predominantly served a geographic HPSA. In order for the MA organization to receive the 10 percent increase, the MA EP would need to provide at least 10 percent or more of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization. In other words, to qualify for the HPSA bonus an MA EP would need to provide more than $24,000 of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization in order to begin earning the HPSA bonus—up to $26,400 to earn the maximum HPSA-enhanced bonus of $19,800 for first payment years 2011 or 2012. Thus, for MA EPs who predominantly furnish services in a geographic HPSA, the ''incentive payment limit'' in § 495.102(b) would be $19,800, instead of $18,000, if the first MA EHR payment year for the MAO with respect to the MA EP were 2011 or 2012. If an MA organization can show that an MA EP predominantly served beneficiaries in a HPSA during the payment year and that that MA EP provided, for example, for the 2011 payment year, at least $26,400 in Part B professional services to MA plan enrollees of the MA organization during the payment year, the MA organization could receive the entire

$19,800 incentive payment for that MA EP. If the MA EP provided less than $26,400 in Part B professional services, the potential incentive payment for that MA EP for that MA organization would be less than $19,800 for the payment year. We are proposing a conforming amendment in § 495.202(b)(2)(ii) to require MA organizations to notify CMS whether the qualifying MA EP predominantly provides covered services to MA plan enrollees in a HPSA.

We also would add a new paragraph (5) to redesignated paragraph (f). This new paragraph (5) would clarify that if—(1) A qualifying MA EP; (2) an entity that employs a qualifying MA EP (or in which a qualifying MA EP has a partnership interest); (3) an MA-affiliated eligible hospital; or (4) any other party contracting with the qualifying MA organization, fails to comply with an audit request to produce documents or data needed to audit the validity of an EHR incentive payment, we will recoup the EHR incentive payment related to the applicable documents or data not produced. While we believe that we presently have the authority to do this under the current § 495.204(e)(4), (to be redesignated as (f)(4)), we believe it would be helpful for the regulations to specifically address what happens in the case of a failure to produce documents or data related to an audit request.

We propose to add a new paragraph (g) to § 495.204 to clarify that in the unlikely event we pay a qualifying MA organization for a qualifying MA EP, and it is later determined that the MA EP—(1) Is entitled to a full incentive payment under the Medicare FFS EHR Incentive Program; or (2) has received payment under the Medicaid EHR Incentive Program, we will recover the funds paid to the qualifying MA organization for such an MA EP from the MA organization. (The former would be in the unlikely event an MA EP appeared to have earned an EHR incentive of less than the full amount under FFS, and then later was determined by FFS to have earned the full amount. In accordance with duplicate payment avoidance provisions in section 1853(l)(3)(B) of the Act and implementing regulations at § 495.208, we would recover the MA EHR incentive payment since a full FFS EHR payment was now due.) If the organization still has an MA contract, we will recoup the amount from the MA organization's monthly payment under section 1853(a)(1)(A) of the Act. If the organization no longer has an MA contract, we will recoup any amounts through other means, such as formal collection. As duplicate and overpayments are prohibited by statute (sections 1853(l)(3)(B), 1853(m)(3)(B), 1903(t)(2) of the Act), we would recover overpaid MA EHR incentive payments for all MA EHR payment years, including payment year 2011.

We also clarify that, in accordance with statutory requirements, if it is determined that an MA organization has received an incentive payment for an MA-affiliated eligible hospital that also received a payment under the Medicare FFS EHR Incentive program or that otherwise should not have received such payment, we will similarly recover the funds paid to the qualifying MA organization for such MA-affiliated eligible hospital from either the MA organization's monthly payment under section 1853(a)(1)(A) of the Act, from the MA-affiliated eligible hospital's CMS payment through the typical process for recouping Medicare funds from a subsection (d) hospital, or through other means such as a collection process, as necessary. As duplicate and overpayments are prohibited by statute, this rule applies beginning with payment year 2011.

4. Avoiding Duplicate Payments

Qualifying MA EPs are eligible for the Medicare FFS EHR incentive payment if they meet certain requirements under that program. However, an EHR incentive payment is only allowed under one program. We believe the requirement that MA organizations notify MA EPs that the MA organization intends to claim them for the MA EHR Incentive Program will minimize misunderstandings among MA EPs (particularly if they expect to receive an incentive payment under the Medicare FFS Incentive Program). It is important for MA EPs to understand certain aspects of the program such as when a qualifying MA organization claims an MA EP under the MA EHR Incentive Program and the MA EP is not entitled to a full FFS EHR Incentive payment, the MA organization would prevent a partial payment under the Medicare FFS EHR Incentive Program from being paid directly to the MA EP.

We propose to require each qualifying MA organization to attest that it has notified the MA EPs it intends to claim. We propose to require that this attestation be submitted along with the MA organization's meaningful use attestation for the MA EHR payment year for which the MA organization is seeking payment.

Therefore, we propose to revise § 495.208 by adding—(1) A new paragraph (a) requiring a qualifying MA organization to notify MA EPs when the MA organization intends to claim them for the MA EHR Incentive Program prior to making its attestation of meaningful use to CMS; (2) a new paragraph (b) requiring qualifying MA organizations to notify MA EPs when they are claiming them, that the MA EPs may still receive an incentive payment under the Medicare FFS or Medicaid EHR Incentive Program, if certain requirements are met; and (3) a new paragraph (c) requiring the qualifying MA organization to attest to CMS that these notification requirements have been satisfied by the MA organization. We also propose to redesignate the current paragraphs (a) through (c) of § 495.208 as (d) through (f), respectively.

As discussed previously, in a revised § 495.210 we are proposing to change the requirement that MA organizations attest to meaningful use within 60 days after the close of the MA EHR payment year for both MA EPs and MA-affiliated eligible hospitals, to a requirement to do so within 2 months in order to provide consistency between the Medicare FFS and MA EHR Incentive Programs.

5. Payment Adjustments Effective for 2015 And Subsequent MA Payment Adjustment Years (§ 495.211).

Beginning in 2015, the Act provides for adjustments to monthly MA payments under sections 1853(l)(4) and 1853(m)(4) of the Act if a qualifying MA organization's potentially qualifying MA EPs or MA-affiliated eligible hospitals (or both) are not meaningful users of certified EHR technology. We are proposing to add a definition of ''MA Payment Adjustment Year'' to the definitions in § 495.200. The definition is needed in part because the payment adjustment phase of the MA EHR program continues indefinitely—beyond the last year for which MA EHR incentive payments can be made to qualifying MA organizations. Additionally, since we are proposing to operationalize MA EHR payment adjustments in a different manner than under the FFS Medicare program, we believe a definition is warranted.

We are proposing that an MA organization must have at least initiated participation in the incentive payment phase of the program from 2011 through 2014 for MA EPs or through 2015 for MA-affiliated eligible hospitals in order to have its Part C payment under section 1853(a)(1)(A) of the Act adjusted during the payment adjustment phase of the program, and must continue to qualify for participation in the program as a ''qualifying MA organization'' as defined for purposes of this program. Such a payment adjustment is also

conditioned on the qualifying MA organization having potentially qualifying MA EPs and MA-affiliated eligible hospitals for the respective payment adjustment years. We take this approach because we believe that it would be impossible to verify that a given MA organization is, in fact, a qualifying MA organization with potentially qualifying MA EPs and MA-affiliated eligible hospitals, unless the MA organization has first demonstrated that it meets these requirements through receipt of MA EHR incentive payments for at least one of the MA EHR payment years as defined for purposes of this program. Note that although MA EHR payment years for both MA EPs and MA-affiliated eligible hospitals can theoretically continue through 2016, the last *first* MA EHR payment year for which an MA organization can receive an EHR incentive payment is 2014 for MA EPs, and 2015 for MA-affiliated hospitals.

Furthermore, we believe payment adjustments under section 1853 of the Act will have limited applicability in the MA EHR Incentive Program because the HITECH Act limits the type of organization that would qualify as a ''qualifying MA organization'' for purposes of the MA EHR Incentive Program in both phases of the program (the phase of the program during which we are making incentive payments, and the phase of the program when we are adjusting payments under sections 1853(l)(4) and 1853(m)(4) of the Act). Section 1853(l)(5) of the Act limits which MA organizations may participate by defining the term ''qualifying MA organization.'' A ''qualifying MA organization'' must be organized as a health maintenance organization (HMO), as defined in section 2791(b)(3) of the Public Health Service (PHS) Act (42 U.S.C. 1395w-23(l)(5)). The PHS Act defines an HMO as a ''Federally qualified HMO, an organization recognized under State law as an HMO, or a similar organization regulated under State law for solvency in the same manner and to the same extent as such an HMO.'' (See 42 U.S.C. 300gg-91). An MA organization participating in Medicare Part C might not be a Federally qualified HMO, nor an organization recognized under State law as an HMO, nor a similar organization regulated under State law for solvency in the same manner and to the same extent as such an HMO. Organizations that do not meet the PHS definition of ''HMO'' cannot receive an incentive payment, nor would they be eligible to have their Part C payment adjusted for having potentially qualifying MA EPs or MA-affiliated eligible hospitals that do not successfully demonstrate meaningful use of certified EHR technology.

Secondly, 1853(l)(2) of the Act requires that MA EPs be as described in that paragraph. The vast majority of MA organizations do not employ their physicians; nor do they use physicians who work for, or who are partners of, an entity that contracts nearly exclusively with the MA organization (as set out in the definition of a ''Qualifying MA EP'' in § 495.200).

Thirdly, section 1853(m)(2) of the Act requires that a qualifying MA organization have common corporate governance with a hospital in order for it to be considered an MA-affiliated eligible hospital, and we do not expect many qualifying MA organizations to meet this test.

The current § 495.202(b)(4) (which is being redesignated as § 495.202(b)(5)) requires all qualifying MA organizations that have potentially qualifying MA EPs or MA-affiliated eligible hospitals that are not meaningful users to initially report that fact to us beginning in June of MA plan year 2015. This reporting requirement would include only qualifying MA organizations that participated in and received MA EHR incentive payments.

There may be MA organizations that participated in the payment phase of the program that no longer, in practice, are qualifying MA organizations, or that no longer have qualifying MA EPs or MA-affiliated eligible hospitals. For example, if a qualifying MA organization that contracted with one entity to deliver physicians' services during the payment phase of the EHR Incentive Program, loses its contract with that entity, or if the entity subsequently contracts with other MA organizations, the MA organization may no longer meet the basic requirements to participate in the program (that is, may no longer be subject to adjustments due to not meeting the 80/80/20 rule). (See § 495.200, for the definition of ''Qualifying MA EP'' in the Stage 1 final rule). Therefore, the MA organization would not necessarily have its monthly payment adjusted because it might no longer meet the basic requirements under which MA EHR incentive payments were made to it.

Therefore, we would adjust payments beginning for payment adjustment year 2015 only for qualifying MA organizations that received MA EHR payments and that have potentially qualifying MA EPs or MA-affiliated eligible hospitals that are not meaningful EHR users. We would rely on the existing self-reporting requirement in redesignated § 495.202(b)(5) and subsequent audits to ensure compliance.

We propose to collect payment adjustments made under sections 1853(l)(4) and 1853(m)(4) of the Act after meaningful use attestations have been made. Final attestations of meaningful use occur after the end of an EHR reporting period, which for MA EPs will run concurrent with the payment adjustment year. In the case of potentially qualifying MA-affiliated eligible hospitals, attestations of meaningful use would occur by the end of November after the EHR reporting period. As noted previously, we are proposing to amend § 495.202(b) to indicate that in addition to initial identification of potentially qualifying MA EPs and MA-affiliated eligible hospitals that are not meaningful users (as required by redesignated § 495.202(b)(5)), qualifying MA organizations will also need to finally identify such MA EPs and MA-affiliated eligible hospitals within 2 months of the close of the applicable EHR reporting period. Final identification by qualifying MA organizations of potentially qualifying MA EPs and/or MA-affiliated eligible hospitals that are not meaningful users will then result in application of a payment adjustment by CMS. On the other hand, final identification of all qualifying MA EPs and/or MA-affiliated eligible hospitals as meaningful users will obviate an adjustment. Through audit we will verify the accuracy of an applicable MA organization's assertions or nonreporting.

We are proposing to adjust one or more of the qualifying MA organization's monthly MA payments made under section 1853(a)(1)(A) of the Act after the qualifying MA organization attests to the percent of hospitals and professionals that either are or are not meaningful users of certified EHR technology. To the extent a formerly qualifying MA organization does not report under § 495.202(b)(4) or (5), we would verify, upon audit, the accuracy of the applicable MA organization's nondisclosure of users.

Under our proposed approach, the adjustment would be calculated based on Part C payment data made under section 1853(a)(1)(A) of the Act for the payment adjustment year. An MA-affiliated eligible hospital must attest to meaningful use by November 30th. Therefore, we could use the Part C payment information in effect at the time of the attestation to calculate the payment adjustment for a specific potentially qualifying MA-affiliated eligible hospital with respect to a

specific MA organization. Although we expect (and prefer) to make an adjustment to one MA monthly payment totaling the adjustment for the year, we request comments on whether more than one monthly payment should be adjusted. One possible approach would be to make this decision on a case-by-case basis depending upon a given qualifying MA organization's situation (for example, payment adjustment amount versus MA organization's monthly payment).

For payment adjustments based on potentially qualifying MA EPs that are not meaningful users of certified EHR technology, we also propose to calculate the adjustment based on the Part C payment made under section 1853(a)(1)(A) of the Act for the payment adjustment year. Because attestations of meaningful use for qualifying MA EPs occur in February of the calendar year following the EHR reporting year, we could calculate the payment adjustment based on the prior MA payment year's payment, and apply that adjustment to one or more of the prospective Part C payments. While we prefer to make an adjustment to one MA prospective payment for the full amount of the payment adjustment when possible, we solicit comment on whether we should make adjustments over several months or in a single month (for the entire adjustment amount), when possible.

Thus, adjustments for MA payment adjustment year 2015 would be based on MA payment data under section 1853(a)(1)(A) of the Act for 2015. However, while the payment adjustment for the 2015 payment adjustment year would be collected as soon as possible, this might not be until CY 2016 through an adjustment to the MA organization's MA capitation payment or payments under section 1853(a)(1)(A) of the Act.

Proposed § 495.211(c) makes clear that the potentially qualifying MA EP and MA-affiliated eligible hospital payment adjustments are calculated separately, and that each adjustment is applied to the qualifying MA organization's monthly payment under section 1853(a)(1)(A) of the Act, as discussed previously.

While proposed paragraphs (a) through (c) would apply to adjustments based on both potentially qualifying and qualifying MA EPs and MA-affiliated eligible hospitals that were not meaningful EHR users, proposed paragraph (d) would apply only to adjustments based on potentially qualifying and qualifying MA EPs that are not meaningful users of certified EHR technology. This paragraph makes clear that if a potentially qualifying MA EP is not a meaningful user of certified EHR technology in payment adjustment year 2015 (and subsequent payment adjustment years), the qualifying MA organization's monthly Part C payment may be adjusted accordingly.

During the payment phase of the MA EHR Incentive Program, qualifying MA organizations attest to meaningful use for each qualifying MA EP and MA-affiliated eligible hospital they are claiming. During the payment adjustment phase of this program, we would need to know the percentage of both qualifying and potentially qualifying MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. This percentage can be derived by taking the total number of the qualifying MA organization's qualifying and potentially qualifying MA EPs or MA-affiliated eligible hospitals and identifying the portion of those MA EPs or MA-affiliated hospitals that are not meaningful EHR users. We would use this percentage to make the adjustment proportional to the percent that are not meaningful users for a given adjustment year and qualifying MA organization.

Moreover, in determining the proportion of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals (those that are not meaningful users), we would exclude EPs and hospitals that were neither qualifying nor potentially qualifying MA EPs in accordance with the definition of ''qualifying'' and ''potentially qualifying MA EPs'' and ''MA-affiliated eligible hospitals'' in § 495.200. Thus, an MA EP that is a hospital-based EP would not be a qualifying or potentially qualifying MA EP since such an EP does not meet the item (5) of the definition of qualifying MA EP in § 495.200 and thus would not be used in our computation of the proportion of MA EPs for purposes of applying the payment adjustment. The formula we are proposing for purposes of applying the payment adjustments proposed in § 495.211(d)(2) with respect to MA EPs is:

[The total number of potentially qualifying MA EPs]/[(the total number of potentially qualifying MA EPs) + (the total number of qualifying MA EPs)].

Similarly, the formula we are proposing for purposes of applying payment adjustments in § 495.211(e)(2)(iii) with respect to MA-affiliated hospitals is:

[The total number of potentially qualifying MA-affiliated eligible hospitals]/[(the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)].

Keeping in mind that redesignated § 495.202(b)(4) and (5) require qualifying MA organizations to identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals and to provide other information beginning for plan year 2015, we are asking for comment on the question of whether, in the payment adjustment phase of this program, qualifying MA organizations with potentially qualifying MA EPs and MA-affiliated eligible hospitals should—(1) still be required to attest to the meaningful use objectives and measures; or (2) instead be required only to report the percent of MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. Commenters should take into account that MA-affiliated eligible hospitals may still be required to perform a reporting function on behalf of their MA-affiliated organization in the National Level Repository (NLR), and are generally bound to ''subsection (d)'' hospital reporting requirements of the NLR, so we are primarily interested in stakeholders' thoughts on the requirements related to MA EPs.

While we wish to minimize burden, we are concerned about our ability to audit the information reported to ensure compliance with MA program requirements. Therefore, should we adopt the proposal in the final rule to require qualifying MA organizations to report only a percentage of MA EPs and MA-affiliated hospitals that are not meaningful users along with identifying information in § 495.202(b)(2)(i) through (iii), we also propose to require such organizations to retain and produce data and records necessary to substantiate their submissions, including evidence of meaningful use by those MA EPs and MA-affiliated eligible hospitals so reported.

We propose that payment adjustments for MA EPs be calculated by multiplying: (1) The percent established under § 495.211(d)(4) of this proposed rule, (which increases the adjustment amount up until 2017 and potentially beyond); with (2) the Medicare Physician Expenditure Proportion; and (3) by the percent of the qualifying MA organization's qualifying and potentially qualifying MA EPs that are not meaningful users. The statute at section 1853(l)(4)(B)(i) of the Act says that the ''percentage points'' in section 1848(a)(7)(A)(ii) of the Act apply to qualifying MA organizations with potentially qualifying MA EPs that are not meaningful users. We would also

apply the additional reductions required under section 1848(a)(7)(A)(iii) of the Act to MA payment adjustments. We propose that if the proportion of MA EPs of a qualifying MA organization did not meet the 75 percent threshold (as determined in proposed § 495.211(d)(2)) in 2018 and subsequent years, the percentage reduction could increase to 4 percent in 2018, 5 percent in 2019 and subsequent years. We also note that we have not proposed the possibility of a 2 percent reduction for 2015 (consistent with the Medicare FFS EHR Incentive Program), because that increased reduction applies in the case of EPs that were subject to an adjustment in 2014 under the e-prescribing program. MA organizations are not independently subject to the e-prescribing payment adjustments. Proposed regulations may be found in § 495.211(d)(4)(iv) through (vi).

The Medicare Physician Expenditure Proportion for a year is the Secretary's estimate of expenditures under Parts A and B that are not attributable to Part C, that are attributable to expenditures for physician services. While this proportion would be uniform across all MA organizations, in accordance with the requirement in section 1853(l)(1) of the Act that payment adjustments be with respect to the eligible professionals described in paragraph (2) of 1853(l) of the Act, we also propose to adjust the proportion on a more individual basis to account for the fact that qualifying MA organizations may contract with a large number of EPs that are neither qualifying nor potentially qualifying. Therefore, we would adjust each MA organization's Physician Expenditure Proportion to recognize that not all of the EPs would meet the nonmeaningful use requirements to be potentially qualifying or qualifying MA EPs. For example, not all EPs might furnish 80 percent of their Title XVIII professional services to enrollees of the qualifying MA organization. Without our proposed adjustment, a small sample size of MA EPs could magnify the reduction amount during the payment adjustment phase of the program, because the actions of a limited set of qualifying and potentially qualifying MA EPs (and whether they meaningfully used certified EHR technology) would determine whether all of an MA organization's physician expenditure proportion was reduced.

An example of our proposed MA payment adjustment for adjustment year 2015 is as follows:

Assume the hypothetical Medicare Physician Expenditure Proportion, adjusted as described previously, is 10 percent for 2015;

The qualifying MA organization's percent of qualifying and potentially qualifying MA EPs that are not meaningful users is 15 percent for 2015; and

The monthly payment in 2015 for the given qualifying MA organization is $10,000,000.

The proposed formula would read as follows:

0.01 (the payment adjustment for 2015) × 0.1 (the hypothetical Medicare Physician Expenditure Proportion) × 0.15 (the percentage of qualifying and potentially qualifying MA EPs that are not meaningful EHR users) × $10,000,000 (monthly Part C payment) × 12 (number of months in the MA payment year) = $18,000 for the entire year, or $1,500 a month. This adjustment would then be collected against one or more of the qualifying MA organization's payments under section 1853(a)(1)(A) of the Act.

In proposed § 495.211(e), we set out a formula for payment adjustments based on potentially qualifying MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology.

The formula would result in an adjustment that is the product of the following:

- Monthly Part C payment for the payment adjustment year;
- The percentage point reduction that applies to FFS hospitals as a result of section 1886(b)(3)(B)(ix)(I) of the Act;
- The Medicare hospital expenditure proportion, adjusted in the same manner as the Physician Expenditure Proportion to recognize that not all hospitals are necessarily qualifying or potentially qualifying MA-affiliated eligible hospitals; and
- The percentage of qualifying and potentially qualifying MA-affiliated eligible hospitals of a given qualifying MA organization that are not meaningful users of certified EHR technology.

The percentage point reduction specified by section 1886(b)(3)(B)(ix)(I) of the Act is based on the point reduction that results when three-fourths of the otherwise applicable percentage increase for the fiscal year is reduced by 33⅓ percent for FY 2015, 66⅔ percent for FY 2016, and 100 percent for FY 2017 and subsequent fiscal years. This has the result of decreasing the otherwise applicable market basket update by one-fourth (for 2015), one-half (for 2016), and three-fourths (for 2017 and subsequent payment adjustment years).

The Medicare Hospital Expenditure Proportion for a year is the Secretary's estimate of expenditures under Parts A and B that are not attributable to Part C, that are attributable to expenditures for inpatient hospital services. As mentioned previously, we propose that this proportion reflect only the MA-affiliated eligible hospitals that are either qualifying or potentially qualifying MA-affiliated eligible hospitals.

We also propose to use the market basket percentage increase that would otherwise apply to ''subsection (d)'' hospitals for an MA payment adjustment year. A hypothetical example would be as follows. The market basket percentage increase for FY 2015 is hypothetically 4 percent. Three-quarters of one-third of 4 percent would be 1 percent. The hypothetical Medicare Hospital Expenditure proportion for the year is 15 percent, and one of two of the relevant MA-affiliated eligible hospitals is not a meaningful EHR user for the applicable period (FY 2015). The monthly payment to the MA organization in 2015 is $10,000,000 a month.

The calculation would be as follows:

0.01 (the market basket percentage point reduction) × 0.15 (the Medicare Hospital Expenditure Proportion) × 0.5 (percent of the qualifying MA organization's qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful users) × $10,000,000 (monthly Part C payment) × 12 (number of months in the MA payment year) = $90,000 for the year, or $7,500 a month. The payment adjustment would be applied on either a monthly basis, or in one adjustment. As stated previously, we request comment on this aspect of the proposed rule.

6. Reconsideration Process for MA Organizations

We propose a new section, § 495.213, which would set forth a reconsideration process for qualifying MA organizations that participate in the MA EHR Incentive Program. Under our proposal certain MA organization reconsiderations would be heard under the appeal process proposed in section II.D.5. of this proposed rule, while others would be heard using the process described in this section. This would allow us to take advantage of another reconsideration mechanism, and ensure consistency in decision-making for reconsiderations relating to, for example, meaningful use determinations.

Although the HITECH Act prohibits both administrative and judicial review of the standards and methods used to determine eligibility and payment (sections 1853(l)(8) and (m)(6) of the

Act, and 42 CFR 495.212), we believe it is prudent to include a process for seeking reconsideration, in certain circumstances, of the application of those standards and methods. For eligibility issues, we would limit reconsiderations to those involving CMS system errors that did not allow the performance of a required function, and the qualifying MA organization or MA-affiliated eligible hospital missed a deadline (such as a registration or attestation deadline) because of such system malfunction. Thus, in § 495.200 we define ''Adverse eligibility determination'' to include only determinations or omissions by CMS caused by a malfunction of a CMS system.

For qualifying MA-affiliated eligible hospitals (either acting on behalf of the qualifying MA organization or where the qualifying MA organization acts on the hospitals' behalf), we would require using the reconsideration process established for hospitals under the FFS EHR Incentive Program (described in section II.D.5. of this proposed rule). Reconsiderations of adverse meaningful use audits would also be heard using the process described in section II.D.5. of this proposed rule.

The remainder of this preamble discussion relates to reconsiderations involving eligibility and payment issues for MA EPs. We would conduct reconsiderations of the application of payment requirements to, and eligibility requirements to participate in the program by a given MA EP under this section. We also request comment as to other issues that may require reconsideration, including a discussion of whether the issues are within our control. For example, if a qualifying MA organization's system incorrectly reports the identities of its qualifying MA EPs to us, we do not believe this could be used as a ground for reconsideration, because such a determination would be outside of our control. Of course, if a qualifying MA organization over-reports, we will recoup the applicable funds related to the over-reporting.

We request comment on defining the terms ''adverse payment determination'' and ''adverse eligibility determination.'' We preliminarily believe the term ''adverse eligibility determination'' should be defined as ''a determination or omission by CMS that prohibits a qualifying MA organization from participating in the EHR Incentive Program, that a representative of the MA organization believes was the result of a malfunction of a CMS system.'' We preliminarily believe the term ''adverse payment determination'' should be defined as ''a determination by CMS that negatively affects an EHR payment determination.''

We also propose to hear reconsiderations of payment adjustment amounts, when that phase of the program occurs.

We propose a two-level reconsideration process. The first level would be a request for an informal reconsideration. The second level would be a final reconsideration.

Requests for informal reconsideration would need to be submitted within 60 calendar days of an adverse eligibility or payment determination. If we find against the MA organization, it will have 30 calendar days from the date on the informal reconsideration decision to file a request for final reconsideration. If the 30th or 60th calendar day (as applicable) is a Saturday, Sunday, or a Federal holiday, the reconsideration request will be due by the next business day. The MA organization would be required to submit all evidence and data in the initial request for informal reconsideration; no new evidence or data would be permitted at the final reconsideration stage. An MA organization could not use the reconsideration process to submit new payment-related information. Failure to file an informal or final reconsideration request pursuant to this CMS process would result in eligibility or payment determinations becoming final and binding, absent CMS reopening due to audit or other evidence of material misrepresentation.

F. Proposed Revisions and Clarifications to the Medicaid EHR Incentive Program

The proposals discussed in this section of the proposed rule would take effect upon finalization of this rule, not when Stage 2 of meaningful use of certified EHR technology takes effect.

1. Net Average Allowable Costs

In this proposed rule, we are formalizing through rulemaking the guidance that was shared with State Medicaid Directors in a letter on April 8, 2011 (available at: *http://www.cms.gov/smdl/downloads/SMD11002.pdf*). These technical changes are required to implement section 205(e) of the Medicare and Medicaid Extenders Act of 2010 (Extenders Act, Pub. L. 111–309). The Extenders Act, enacted on December 15, 2010, amended sections 1903(t)(3)(E) and 1903(t)(6)(B) of the Act. The amended sections change the requirements for an EP to demonstrate the ''net average allowable costs,'' the contributions from other sources, and the 15 percent provider contribution requirements to participate in the Medicaid EHR Incentive Payment Program. The Extenders Act provided that an EP has met this responsibility, as long as the incentive payment is not in excess of 85 percent of the net average allowable cost ($21,250 for first year payments).

Before the Extenders Act, Medicaid EPs who wanted to participate in the EHR Incentive Payment Program were required to provide documentation of certain costs related to acquiring and implementing certified EHR technology. The Extenders Act amended the relevant statute by allowing for providers to simply document and attest that they have adopted, implemented, upgraded, or meaningfully used certified EHR technology, while allowing us to set these average costs.

As a result, rather than requiring each EP to calculate the payments received from outside sources, each will use the average costs and contribution amount we established. After conducting a meta-analysis of existing data of an EP's costs to adopt, implement, or upgrade certified EHR technology, we determined that average contributions from outside sources should not exceed $29,000. The documentation originally required by an EP to demonstrate that he or she contributed 15 percent (for example, $3,750 for year 1) of the ''net average allowable costs'' is also no longer needed. The Act now provides that an EP has met this responsibility as long as the incentive payment is not in excess of 85 percent of the net average allowable cost ($21,250). Given that this change is already in effect, we propose to remove from the required content in the State Medicaid HIT Plan, the requirement that States describe the process in place to ensure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology, as described in § 495.332.

TABLE 16—DETERMINATION OF NET AVERAGE ALLOWABLE COSTS FOR THE FIRST PAYMENT YEAR

First year variables[1]	Amounts	Prior to extenders act changes	Currently
Average Allowable Costs	$54,000	Determined through a CMS meta-analysis, described in both the proposed rule (75 FR 1844) and the final rule (75 FR 44314).	No change.
Contributions from Other Sources	Does not exceed $29,000	Subtracted from Average Allowable Costs to reach "Net" Average Allowable Costs. An EP was required to show documentation of all contributions from certain other sources.	No documentation is needed. We have determined that average contributions do not exceed $29,000.
Capped Amount of "Net" Average Allowable Costs.	$25,000	Capped by statute and designated in CMS final rule.	No change.
Contribution from the EP	$3,750	An EP was required to demonstrate that he or she had contributed at least 15 percent of the net average allowable costs towards a certified EHR.	No documentation needed. Determined to have been met by virtue of EP receiving no more than $21,250 in the first payment year.
Incentive payment[2]	$21,250	85 percent of the Net Average Allowable Costs; determined through statute. An EP could receive less than this amount if he or she had contributions from other sources exceeding $29,000.	All EPs will receive the maximum incentive payment of $21,250, as all EPs will be determined to have contributions from other sources under $29,000.

[1] These same concepts (but not figures) apply to the second through sixth years, integrating the figures from the stage 1 final rule. Ultimately, the incentive paid in the second through sixth years is still the statutory maximum of $8,500.

[2] This figure is further reduced to two-thirds for pediatricians qualifying with reduced Medicaid patient volumes. This is described at 42 CFR 495.310.

2. Eligibility Requirements for Children's Hospitals

We propose to revise the definition of a children's hospital in § 495.302 to also include any separately certified hospital, either freestanding or hospital within hospital that predominately treats individuals under 21 years of age, and that does not have a CMS certification number (CCN) because they do not serve any Medicare beneficiaries but has been provided an alternative number by CMS for purposes of enrollment in the Medicaid EHR Incentive Program. We will provide future guidance on how to obtain these alternative numbers.

3. Medicaid Professionals Program Eligibility

Section 1903(t) of the Act authorizes Medicaid payments to encourage the adoption and use of certified EHR technology, and places Medicaid patient volume requirements on EPs to qualify for such payments under the Medicaid program. Patient volume requirements ensure that Medicaid funding is used to encourage the adoption and use of technology specifically for care of Medicaid populations. Otherwise, Medicaid funding could potentially be used to fund adoption and use of technology that does not benefit the Medicaid population directly. Therefore, we propose that at least one of the clinical locations used for the calculation of an EPs' patient volume have certified EHR technology during the payment year for which the EP is attesting to adopt, implement or upgrade in their first participation year, or to meaningful use in subsequent years. This will ensure that EPs receive Medicaid funding for certified EHR technology that is used on behalf of the EP's Medicaid patients. We have amended § 495.304 and § 495.332 accordingly.

a. Calculating Patient Volume Requirements

We propose to revise § 495.306 (c) to allow States the option for their providers to calculate total Medicaid or total needy individual patient encounters in any representative, continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation. This option would be in addition to the current regulatory language basing patient volume on the prior calendar or fiscal year. We believe this adjustment would provide greater flexibility in eligible providers' patient volume calculations.

Likewise, we propose to revise § 495.306(d)(1)(i)(A) to allow for the calculation of the total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the preceding calendar year, as is currently permitted, or in the 12 months preceding the EPs' attestation when at least 1 Medicaid encounter took place with the Medicaid patient in the 24 months prior to the beginning of the 90-day period. Also, we propose to revise § 495.306(d)(1)(ii)(A) accordingly, so that the numerator and denominator are using equivalent periods. Conforming changes would be made to § 495.306(d)(2)(i) and (ii) for needy individual patient volume. We are proposing these changes to account for new clinical guidelines from the U.S. Preventive Health Services Task Force that allow greater spacing between some wellness visits. Therefore, in order for a patient to be considered ''active'' on a provider's panel, we propose 24 months is more appropriate. This change is also in order to be consistent with the proposed Stage 2 meaningful use measure for patient reminders sent to ''active patients.''

We propose to expand the current definition of ''encounter'' to also include any service rendered on any one day to an individual ''enrolled'' in a Medicaid program. Such a definition would ensure that patients enrolled in a Medicaid program are counted, even if the Medicaid program did not pay for the service (because, for example, a third party payer paid for all of the item or service or the service is not covered under Medicaid). The definition would

also include encounters for patients who are Title XIX eligible and who meet the definition of ''optional targeted low income children'' under section 1905(u)(2) of the Act. Thus, individuals in Title XXI-funded Medicaid expansions (but not separate CHIP programs) could be counted in providers' patient volume calculations. This approach is consistent with existing policies that provide Title XIX protections to children enrolled in Title XXI-funded Medicaid expansions.

As of 2010, 33 States have Title XXI Medicaid expansions via approved State plan amendments. Therefore, providers in those States would be able to include encounters with individuals in such expansions in their patient volume calculation for purposes of this program. In 2010, over 2.1 million children were covered in Medicaid expansion programs. We expect this change would increase the number of eligible providers who qualify for the Medicaid EHR Incentive Program, particularly those serving children. We expect that this change would represent an increase because States were more limited in their inclusion of Medicaid expansion populations based upon the July 28, 2010 final rule.

We understand that multiple providers may submit an encounter for the same individual. For example, it may be common for a PA or NP to provide care to a patient, then a physician to also see, or invoice for services to that patient. We clarify that it is acceptable in these and similar circumstances to count the same encounter for multiple providers for purposes of calculating each provider's patient volume when the encounters take place within the scope of practice.

b. Practices Predominantly

Similar to our proposed revisions for patient volume, we propose to revise the definition of ''practices predominantly'' at § 495.302. EPs could use either: (1) The most recent calendar year; or (2) the most recent 12 months prior to attestation.

4. Medicaid Hospital Incentive Payment Calculation

a. Discharge Related Amount

In order to ensure that Medicaid regulations are consistent with Medicare, we are proposing that the Medicaid calculation should be consistent with the Medicare calculation found in § 495.104(c)(2). Our current regulations at § 495.310(g)(1)(i)(B) require the use of the ''12-month period selected by the State, but ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year.'' We also published a tip sheet with additional guidance on the Medicaid hospital incentive payment calculation, which can be found at: (*https://www.cms.gov/MLNProducts/downloads/Medicaid_Hosp_Incentive_Payments_Tip_Sheets.pdf*). However, some hospitals may not have a full 12 months of data ending with the Federal fiscal year immediately preceding the first payment year, or they may have a slightly older 12-month period that could be used. Therefore, we are revising our policy to allow States to use, for the purpose of calculating the discharge related amount, and other determinations (such as inpatient bed days, the most recent continuous 12-month period for which data are available prior to the payment year. If such 12-month period is a cost report, it should be one, single 12-month cost reporting period (and not a consolidation of two separate cost reporting periods). If it is an alternative source different from the cost report, we would rely on the State to ensure that the source is an appropriate source, and that the period is a continuous 12 months, and that the State is using the most recent data that is available.

b. Acute Care Inpatient Bed Days and Discharges for the Medicaid Share and Discharge-Related Amount

We currently require that only discharges from the acute care part of the hospital are allowable to be counted in both the discharge-related amount and the Medicaid share. For example, in response to a frequently asked question (available at *https://questions.cms.hhs.gov/app/answers/detail/a_id/10361*) we explained that nursery days and nursery discharges (for newborns) could not be counted in both the Medicare and Medicaid EHR incentive programs. We stated: ''[N]ursery days and discharges are not included in inpatient bed-day or discharge counts in calculating hospital incentives * * * because they are not considered acute inpatient services based on the level of care provided during a normal nursery stay.'' Also, we explained that the Medicaid payment to hospitals is based largely on the method that applies to Medicare incentive payments. Because such nursery discharges and bed-days would not be included in the Medicare calculation, and because the Medicaid statute incorporates Medicare concepts, they also would not be counted in the Medicaid formula.

In order to ensure that the regulations accurately reflect our current policy, we propose to amend the hospital payment regulations at § 495.310(g)(1)(i)(B) and (g)(2) to recognize that only acute-care discharges and bed-days are included in our calculations.

Such regulatory amendments do not represent a change in policy but rather a clarification of existing policy. The Medicaid share would count only those days that would count as inpatient-bed days for Medicare purposes under section 1886(n)(2)(D) of the Act. (See 75 FR 44498). In addition, in determining the overall EHR amount, section 1903(t)(5)(B) of the Act requires the use of applicable amounts specified in section 1886(n)(2)(A) of the Act.

c. Hospitals Switching States

There may be a situation where a hospital changes participation in one State Medicaid EHR incentive program to participation in another State. We are clarifying that in no case will a hospital receive more than the aggregate incentive amount calculated by the State from which the hospital initiated participation in the program. Section 495.310(e) requires a hospital to choose only 1 State per payment year from which to receive an incentive payment. Additionally, § 495.310(f)(2) states that in no case can total incentives received by a hospital exceed the aggregate EHR incentive amount, as calculated in § 495.310(g).

In this scenario, both States would be required to work together to determine the remaining payments due to the hospital based on the aggregate incentive amount and incentive amounts already paid. The hospital would then assume the second State's payment cycle less the money that was paid from the first State. States should consult with us before addressing this specific scenario.

5. Hospital Demonstrations of Meaningful Use—Auditing and Appeals

We are proposing revisions to § 495.316 under which we would conduct meaningful use audits and any subsequent appeals of such audits of any participating hospitals, including those that are eligible for only the Medicaid EHR Incentive program. In section 1903(t)(6)(C)(II) of the Act, all demonstrations of meaningful use must be ''acceptable to the Secretary'' and may be based upon methods that are adopted under the Medicare program in section 1886(n) of the Act. Thus, under this standard, we would require that all Medicaid hospitals would be subject to audit and appeal by CMS just for demonstrations of meaningful use. Therefore, States will continue to provide the remaining audit functions for requirements under the Medicaid

EHR Incentive Program. In addition (as discussed later), as we would be conducting the audit, hospitals would be subject to the CMS appeals process for any disputes regarding audit findings related to meaningful use, and States would be bound by our determinations regarding meaningful use findings. We have proposed to revise the SMHP requirements in § 495.332 to clarify that States must indicate that if they are in agreement that they would be bound by our audit and appeal determinations in these circumstances. We also would revise our regulations at § 495.370 to make clear that appeals of adverse CMS audits would be subject to the CMS administrative appeals process and not the State administrative process.

We believe it is essential for us to conduct the audits and appeals of hospital meaningful use because most hospitals are eligible for both Medicare and Medicaid incentive payments, submit attestations on meaningful use to us under the Medicare attestation system, and, if successful, under the authority of section 1903(t)(8) of the Act, are deemed to have met the meaningful use requirements for Medicaid. This proposed revision would alleviate the burden on States developing processes, for which many States have indicated interest, and devoting resources to audit hospitals' meaningful use attestations when we estimate that a majority of States would have two or fewer Medicaid-only hospitals apply for incentive payments. Instead, we would leverage the resources we would have already devoted to auditing the vast majority of hospitals eligible for both incentive programs, to include the approximately 150 hospitals that are only eligible for Medicaid incentives. The meaningful use attestation data collected by States for the Medicaid-only eligible hospitals will be shared with our auditors to enable this process. We are not proposing to audit Medicaid eligible professionals because the anticipated number of Medicaid eligible professionals demonstrating meaningful use would not provide the same level of cost/resource efficiency. However, we are leveraging our work in designing and implementing Medicare EP meaningful use audits by sharing strategic approaches with States. States will remain responsible for auditing all other aspects of eligibility for both EPs and eligible hospitals for incentive payments, including, but not limited to—(1) Adopt, implement or upgrade; (2) patient volume; (3) average stay length; and (4) calculation of payment amounts. States would also remain responsible for auditing EPs for compliance with meaningful use of certified EHR technology.

Please note that right to audit discussed in this proposed rule is in addition to, and not in lieu of, any other applicable rights to audit, such as those held by the Office of the Inspector General (OIG). We do not intend for anything in this rule to limit or restrict the authority of another Federal agency or another office within the Department of Health & Human Services to audit, evaluate, investigate, or inspect.

6. State Medicaid Health Information Technology Plan (SMHP) and Implementation Advance Planning Document (IAPD)

a. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates

We are proposing to revise § 495.342 regarding the frequency of HIT IAPD updates. Rather than requiring each State to submit an annual HIT IAPD within 60 days from the HIT IAPD approved anniversary date, we propose to require that a State's annual IAPD (also known as an IAPD Update (IAPD–U)) be submitted a minimum of 12 months from the date of the last CMS approved HIT IAPD. For example, if the initial HIT IAPD or previous IAPD–U was approved by CMS effective July 25, 2011, the State must submit their next HIT IAPD–U on or before July 25, 2012. Therefore, annual IAPD updates are required only if the State has not submitted an IAPD–U in the past 12 months, rather than on a fixed annual basis as currently reflected in § 495.342. We are not changing the requirements of the circumstances of ''as needed'' IAPD updates as defined by § 495.340.

b. Requirements of States Transitioning from HIT Planning Advanced Planning Documents (P–APDs) to HIT IAPDs

We are proposing the following process for States that have had an HIT P–APD approved by CMS, and are ready to submit a HIT IAPD for review and approval. We do not allow States to have more than one HIT Advance Planning Document (APD) open at a time. If planning activities from the HIT P–APD have been completed, the State should explain in a narrative format to be included in the HIT IAPD that all planning activities have been completed and the planning advanced planning document can be closed out. If there are HIT planning activities that the State determines will continue to be ongoing during the implementation period, these planning activities must be included as line items within the HIT IAPD budget.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

This analysis serves as a revision to the existing PRA package approved under OMB control number 0938–1158. The following is a discussion of the new information collection requirements contained in this proposed regulation that we believe are subject to PRA. The projected numbers of EPs, eligible hospitals, and CAHs, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated Federal costs and savings in the section V of this proposed rule. The actual burden would remain constant for all of Stage 2 as the EHR reporting period would be the entire calendar year for EPs and Federal fiscal year for eligible hospitals and CAHs. The only variable from year to year in Stage 2 would be the number of respondents, as noted in the Impact Analysis Assumptions. For the purposes of this analysis, we are focusing only on 2014, the first year in which a provider may participate in Stage 2 the Medicare EHR Incentive Program. We do not believe the burden for EPs, eligible hospitals and CAHs participating in Stage 1 prior to 2014 will be different from the Agency Information Collection Activities (75 FR 65354) based on this proposed rule. Beginning in 2012, Medicare EPs, eligible hospitals, and CAHs have the option to electronically

report their clinical quality measures through the respective electronic reporting pilots. The burden for the EP pilot is discussed in the CY 2012 Medicare Physician Fee Schedule final rule with comment period (76 FR 73422 through 73425). For eligible hospitals and CAHs, the burden is discussed in the CY 2012 Hospital Outpatient Prospective Payment final rule with comment period (76 FR 74489 through 74492).

A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.6 and § 495.8)

In § 495.6, we propose that to successfully demonstrate meaningful use of certified EHR technology for Stage 2, an EP, eligible hospital or CAH (collectively referred to as ''provider'' in this section) must attest, through a secure mechanism in a specified manner, to the following during the EHR reporting period: (1) The provider used certified EHR technology and specified the technology was used; and (2) the provider satisfied each of the applicable objectives and associated measures in § 495.6. In § 495.8, we propose that providers must also successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable. We estimate that the certified EHR technology adopted by the provider will capture many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We also expect that the provider will enable the functionality required to complete the objectives and associated measures that require the provider to attest that they have done so.

We propose that EPs would be required to report on a total of 17 core objectives and associated measures, 3 of 5 menu set objectives and associated measures, and 12 ambulatory clinical quality measures. We propose that eligible hospitals and CAHs would be required to report on a total of 16 core objectives and associated measures, 2 of 4 menu set objectives and associated measures, and 24 clinical quality measures.

There are 13 core objectives and up to 2 menu set objectives that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest they have met 11 core objectives and 4 menu set objectives that require numerators and denominators. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider would maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or their designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated, as well as each CQM for providers attesting in their first year of the program.

Additionally, providers will be required to report they have completed objectives and associated measures that require a ''yes'' or ''no'' response during attestation. For EPs, there are 3 core objectives and up to 3 menu set objectives that would require a ''yes'' or ''no'' response during attestation. For eligible hospitals and CAHs, there are 4 core objectives and that would require a ''yes'' or ''no'' response during attestation and no such menu set objectives. We expect that it would take a provider or their designee 1 minute to attest to each objective that requires a ''yes'' or ''no'' response.

Providers would also be required to attest that they are protecting electronic health information. We estimate completion of the analysis required to successfully meet the associated measure for this objective will take approximately 6 hours, which is identical to our estimate for the Stage 1 requirement. This burden estimate assumes that covered entities are already conducting and reviewing these risk analyses under current HIPAA regulations. Therefore, we have not accounted for the additional burden associated with the conduct or review of such analyses.

Table 17 lists those objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the core set of objectives and associated measures will take an EP 8 hours 12 minutes to complete, and will take an eligible hospital or CAH 7 hours 54 minutes to complete. For EPs, we estimate the completion of 3 menu set objectives and associated measures will take between 3 minutes and 21 minutes to complete, depending on the combination of objectives they choose to attest to. For EPs, we estimate the selection, preparation, and electronic submission of the 12 ambulatory clinical quality measures would take 2 hours. We estimate it would take eligible hospitals and CAHs 20 minutes to attest to the 2 menu set objectives they choose. For eligible hospitals and CAHs, we estimate the selection, preparation, and electronic submission of 24 required clinical quality measures would take 4 hours.

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TABLE 17: BURDEN ESTIMATES

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
CORE SET	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.	More than 60 percent of medication, laboratory, and radiology orders created by the EP or authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	10 minutes	10 minutes
	Generate and transmit permissible prescriptions electronically (eRx)		More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.	10 minutes	
	Record the following demographics - Preferred Language - Gender - Race - Ethnicity - Date of birth	Record the following demographics - Preferred Language - Gender - Race - Ethnicity - Date of birth - Date and preliminary cause of death in the event of mortality	More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data	10 minutes	10 minutes
	Record and chart changes in vital signs: - Height - Weight - Blood pressure (age 3 and over) - Calculate and display BMI - Plot and display growth chart for patients 0-20 years, including BMI	Record and chart changes in vital signs: - Height - Weight - Blood pressure (age 3 and over) - Calculate and display BMI - Plot and display growth chart for patients 0-20 years, including BMI	More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), blood pressure (for patients age 3 and over only) and height and weight (for all ages) recoded as structured data	10 minutes	10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	More than 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data	10 minutes	10 minutes
	Use clinical decision support to improve performance on high-priority health conditions	Use clinical decision support to improve performance on high-priority health conditions	1. Implement five clinical decision support interventions related to five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period. 2. The EP, eligible hospital, or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	1 minute	1 minute
	Incorporate clinical lab-test results into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	More than 55 percent of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23 during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data	10 minutes	10 minutes
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.	1 minute	1 minute
	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care		More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting	10 minutes	

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
			period were sent a reminder, per patient preference		
		Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)	More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR.. .		1 minute
	Provide patients the ability to view online, download and transmit their health information within 24 hours of an encounter or within four business days of the information being available to the EP.		1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient within 24 hours of the encounter or within 3 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information 2. More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view and are provided the capability to download their health information	10 minutes	
		Provide patients the ability to view online and download information about a hospital admission	1. More than 80 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or		10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
			23) of an eligible hospital or CAH view or download their information during the reporting period		
	Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.	10 minutes	
	Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient	Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient	For more than 10 percent of all office visits by the EP, patients are provided patient-specific education resources identified by Certified EHR Technology. More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient and emergency departments (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.	10 minutes	10 minutes
	Use secure electronic messaging to communicate with patients on relevant health information		A secure message was sent using the electronic messaging function of Certified EHR Technology for more than 10 percent of unique patients seen during the EHR reporting period	10 minutes	
	The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	10 minutes	10 minutes
	The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide	1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions	10 minutes	10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	each transition of care or referral.	summary care record for each transition of care or referral.	of care and referrals. 2. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals..		
	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system from the beginning to the end of the EHR reporting period	1 minute	1 minute
		Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies from the beginning to the end of the EHR reporting period as authorized, and in accordance with applicable State law and practice.		1 minute
		Capability to submit electronic syndromic surveillance data to public health agencies, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency from the date of initiation to the end of the EHR reporting period		1 minute
	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308 (a)(1), including addressing the	6 hours	6 hours

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	technical capabilities	technical capabilities.	encryption/security of data at rest and implement security updates as necessary and correct identified security deficiencies as part of its risk management process		
		Core Set Burden		8 hours 12 minutes	7 hours 54 minutes
MENU SET		Record whether a patient 65 years old or older has an advance directive	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.		10 minutes
	Incorporate imaging results and information into Certified EHR Technology	Incorporate imaging results and information into Certified EHR Technology	More than 40 percent of all scans and tests whose result is an image ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are incorporated into Certified EHR Technology	10 minutes	10 minutes
	Record patient family health history as structured data	Record patient family health history as structured data	More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives or an indication that family health history has been reviewed	10 minutes	10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		Generate and transmit permissible discharge prescriptions electronically (eRx)	More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are transmitted electronically using Certified EHR Technology		10 minutes
	Capability to submit electronic syndromic surveillance data to public health agencies, and in accordance with applicable law and practice		Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency from the beginning to the end of the EHR reporting period	1 minute	
	Capability to identify and report cancer cases to a State cancer registry where authorized, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry from the beginning to the end of the EHR reporting period	1 minute	
	Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period	1 minute	
	Menu Set Least Burdensome Criteria			3 minutes	20 minutes
	Menu Set Most Burdensome Criteria			21 minutes	20 minutes
	Time to Attest and Report Clinical Quality Measures			2 hours	4 hours
	Total - Core Set (including CQMs) + Least Burdensome Menu Set Criteria			10 hours 15 minutes	12 hours 14minutes
	Total - Core Set (including CQMs) + Most Burdensome Menu Set Criteria			10 hours 33 minutes	12 hours 14minutes

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First, we will discuss the burden associated with the EP attestation to meeting the core meaningful use objectives and associated measures. We estimate that it will take no longer than 8 hours and 12 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specify the EHR technology used and satisfied each of the applicable core objectives and associated measures. We estimate it will take an EP 21 minutes if they choose to submit the most burdensome objectives and associated measures from the menu set. If an EP chooses to attest to the least burdensome menu set objectives and associated measures, we estimate this will take no longer than 3 minutes. We also estimate that it will take an EP an additional 2 hours to select, prepare, and electronically submit the ambulatory clinical quality measures. The total burden hours for an EP to attest to the most burdensome criteria previously specified is 10 hours 33 minutes. The total burden hours for an EP to attest to the least burdensome criteria previously specified is 10 hours 15 minutes. We estimate that there could be approximately 537,600 non-hospital-based Medicare and Medicaid EPs in 2014. We anticipate approximately 37% (198,912) of these EPs may attest to the information previously specified (after registration and completion of Stage 1) in CY 2014 to receive an incentive payment. We estimate the burden for the approximately 13,000 MA EPs in the MAO burden section. We estimate the total burden associated with these requirement for an EP is 10 hours 33 minutes (8 hours 12 minutes + 21 minutes + 2 hours). The total estimated annual cost burden for all EPs to attest to EHR technology, meaningful use core set and most burdensome menu set criteria, and electronically submit the ambulatory clinical quality measures is $188,783,003 (198,912 EPs × 10 hours 33 minutes × $89.96 (mean hourly rate for physicians based on May 2010 Bureau of Labor Statistics (BLS data)). We estimate the total burden associated with these requirement for an EP is 10 hours 15 minutes (8 hours 12 minutes + 3 minutes + 2 hours). The total estimated cost burden for all EPs to attest to EHR technology, meaningful use core set and least burdensome menu set criteria, and electronically submit the ambulatory clinical quality measures is $183,414,766 (198,912 EPs × 10 hours 15 minutes × $89.96 (mean hourly rate for physicians based on May 2010 BLS data)). We invite public comments on the estimated percentages and numbers of (registered) EPs that will attest to the aforementioned criteria because such information would help us more accurately determine the burden on the EPs.

Similarly, eligible hospitals and CAHs will attest that they have met the core meaningful use objectives and associated measures, and will electronically submit the clinical quality measures. We estimate that it will take no longer than 7 hours and 54 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specify the EHR technology used, and satisfied each of the applicable core objectives and associated measures. We estimate it will take an eligible hospital or CAH 20 minutes to choose and submit the objectives and associated measures from the menu set. We also estimate that it will take an eligible hospital or CAH an additional 4 hours to select, prepare, and electronically submit the clinical quality measures. Therefore, the total burden hours for an eligible hospital or CAH to attest to the aforementioned criteria is 12 hours 14 minutes. We estimate that there are about 4,993 eligible hospitals and CAHs (3,573 acute care hospitals, 1,325 CAHs, 84 children's hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria (after registration and completion of Stage 1) in FY 2014 to receive an incentive payment. We estimate the burden for the 30 MA-affiliated hospitals in section III.B. of this proposed rule. We estimate the total burden associated with these requirements for an eligible hospital or CAH is 12 hours 14 minutes (7 hours 54 minutes + 20 minutes + 4 hours). The total estimated annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use core set and menu set criteria, and electronically submit the clinical quality measures is $2,375,564 (4,993 eligible hospitals and CAHs × $62.23 (12 hours 14 minutes × $62.23 (mean hourly rate for lawyers based on May 2010 BLS) data)). We invite public comments on the estimated percentages and numbers of (registered) eligible hospitals and CAHs that will attest to the aforementioned criteria because such information would help use more accurately determine the burden on the eligible hospitals and CAHs. We also invite comments on the type of personnel or staff that would most likely attest on behalf of the eligible hospital or CAH.

B. ICRs Regarding Qualifying MA Organizations (§ 495.210)

We estimate that the burden would be significantly less for qualifying MA organizations attesting to the meaningful use of their MA EPs in Stage 2, because—(1) Qualifying MA organizations do not have to report the ambulatory clinical quality measures for their qualifying MA EPs; and (2) qualifying MA EPs use the EHR technology in place at a given location or system, so if certified EHR technology is in place and the qualifying MA organization requires its qualifying MA EPs to use the technology, qualifying MA organizations will be able to determine at a faster rate than individual FFS EPs, that its qualifying MA EPs meaningfully used certified EHR technology. In other words, qualifying MA organizations can make the determination en masse if the certified EHR technology is required to be used at its facilities, whereas under FFS, each EP likely must make the determination on an individual basis. We estimate that, on average, it will take an individual 45 minutes to collect information necessary to determine if a given qualifying MA EP has met the meaningful use objectives and measures, and 15 minutes for an individual to make the attestation for each MA EP. Furthermore, the individuals performing the assessment and attesting will not likely be eligible professional, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 9, step 1, with an hourly rate of approximately $25.00/hour, and the person attesting (and who may bind the qualifying MA organization based on the attestation) could be equivalent to a GS 15, step 1, or approximately $59.00/hour. Therefore, for the approximately 13,000 potentially qualifying MA EPs, we believe it will cost the participating qualifying MA organizations approximately $435,500 annually to make the attestations ([9,750 hours × $25.00] + [3,250 hours × $59.00]).

Furthermore, MA-affiliated eligible hospitals will be able to complete the attestations slightly faster than eligible hospitals because MA-affiliated eligible hospitals do not have to report the hospital clinical quality measures. While it is estimated that it will take an eligible hospital or CAH approximately between 16 hours 24 minutes and 16 hours 33 minutes to attest to the applicable meaningful use objectives and associated measures, 8 of those hours are attributed to reporting clinical quality measures, which MA organizations do not have to report.

Therefore, we estimate that it will take between 8 hours 24 minutes and 8 hours 33 minutes, (which on average is 8 hours 29 minutes) for an MA organization's MA-affiliated eligible hospitals to make the attestations. We believe that the individual gathering the information could be equivalent to a GS 9, step 1, with an hourly rate of approximately $25.00/hour, and the person attesting (and who may bind the qualifying MA organization based on the attestation) could be equivalent to a GS 15, step 1, or approximately $59.00/hour. We believe that the person gathering the information could dedicate 7 of the estimated hours to gathering the information, and the individual certifying could take 1 hour 29 minutes of the estimated time. Therefore, for the approximately 30 potentially qualifying MA-affiliated eligible hospitals, we believe it will cost the participating qualifying MA organizations in the aggregate approximately $7,870 annually to successfully attest ([210 hrs × $25.00] + [44 hrs × $59.00]).

C. ICRs Regarding State Medicaid Agency and Medicaid EP and Hospital Activities (§ 495.332 through § 495.344)

The burden associated with this section is the time and effort associated with completing the single provider election repository and each State's process for the administration of the Medicaid incentive payments, including tracking of attestations and oversight; the submission of the State Medicaid HIT Plan and the additional planning and implementation documents; enrollment or reenrollment of providers, and collection and submission of the data for providers to demonstrate that they have adopted, implemented, or upgraded certified EHR technology or that they are meaningful users of such technology. We believe the burden associated with these requirements has already been accounted for in our discussion of the burden for § 495.316. However, we are proposing to revise 42 CFR 495 regarding the frequency of HIT IAPD updates. Rather than requiring each State to submit an annual HIT IAPD within 60 days from the HIT IAPD approved anniversary date, we are proposing to require that a State's annual IAPD or IAPD Update (IAPD–U) be submitted at a minimum of 12 months from the date of the last CMS approval. Therefore, annual IAPD updates are only required if the State has not submitted an IAPD–U in the past 12 months, which we create less of a burden on the States. We expect that it would take a State 70 hours to update an annual IAPD. We believe that the proposed requirements for States to agree to have CMS conduct audits and appeals for hospitals for meaningful use will reduce State burden, as they will not conduct their own audits. Also, proposed alternatives for calculating patient volume will alleviate State burden as patient volume will be more easily calculated.

TABLE 18—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING REQUIREMENTS

Reg section	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.6—EHR Technology Used, Core Set Objectives/Measures incl. CQMs (EPs)	0938–New	198,912	198,912	8.20	1,631,078	$89.96	$146,731,812.86
§ 495.6—Menu Set Objectives/Measures (EPs) HIGH	0938–New	198,912	198,912	0.35	69,619	89.96	6,262,943.23
§ 495.6—Menu Set Objectives/Measures (EPs) LOW	0938–New	198,912	198,912	0.05	9,946	89.96	894,706.18
§ 495.6—Menu Set Objectives/Measures (EPs) AVERAGE	0938–New	198,912	198,912	0.20	39,782	89.96	3,578,824.70
§ 495.8—CQMs for EPs	0938–New	198,912	198,912	2.00	397,824	89.96	35,788,247.04
§ 495.6—EHR Technology Used, Core Set Objectives/Measures (hospitals/CAHs)	0938–New	2,696	2,696	7.90	21,298	62.23	1,325,399.43
§ 495.6—Menu Set Objectives/Measures (hospitals/CAHs)	0938–New	2,696	2,696	0.33	890	89.96	80,035.61
§ 495.8—CQMs for hospitals/CAHs	0938–New	2,696	2,696	4.00	10,784	89.96	970,128.64
§ 495.210—Gather information for attestation (MA EPs)	0938–New	13,000	13,000	0.75	9,750	25.00	243,750.00
§ 495.210—Attesting on behalf of MA EPs	0938–New	13,000	13,000	0.25	3,250	59.00	191,750.00
§ 495.210—Total cost of attestation for Stage 2 (MA EPs)	0938–New	13,000	13,000	1.00	13,000	n/a	435,500.00
§ 495.210—Gather information for attestation (MA-affiliated hospitals)	0938–New	30	30	7.00	210	25.00	5,250.00
§ 495.210—Attesting on behalf of MA-affiliated hospitals	0938–New	30	30	1.48	44	59.00	2,619.60
§ 495.210—Total cost of attestation for Stage 2 (MA-affiliated hospitals)	0938–New	30	30	8.48	254	n/a	7,869.60
§ 495.342—1. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates	0938–New	56	56	70.00	3,920	56.24	220,460.80
Burden Total for 2014	.....	.....	.....	.....	2,118,831.28	.....	189,138,279

Note: All non-whole numbers in this table are rounded to 2 decimal places.

If you would like to comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–0044–P] Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would implement the provisions of the ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use certified EHR technology. The proposed rule specifies applicable criteria for earning incentives and avoiding payment adjustments.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is anticipated to have an annual effect on the economy of $100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rule.

As noted in section I. of this proposed rule, this proposed rule is one of two coordinated rules related to the adoption and meaningful use of certified EHR technology. The other is ONC's proposed rule, titled ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' published elsewhere in this **Federal Register**. This analysis focuses on the impact associated with Stage 2 requirements for meaningful use, the changes in quality measures that will take effect beginning in 2014, and other changes being proposed for the Medicare and Medicaid EHR Incentive Programs.

A number of factors will affect the adoption of EHR systems and demonstration of meaningful use. Many of these factors are addressed in this analysis and in the proposed provisions of the rule titled ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' published elsewhere in this **Federal Register.** Readers should understand that these forecasts are also subject to substantial uncertainty since demonstration of meaningful use will depend not only on the standards and requirements for FYs 2014 and 2015 for eligible hospitals and CYs 2014 and 2015 for EPs, but on future rulemakings issued by the HHS.

The Act provides Medicare and Medicaid incentive payments for the meaningful use of certified EHR technology. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. Payment adjustments are incorporated into the Medicare program for providers unable to demonstrate meaningful use. The absolute and relative strength of these is unclear. For example, a provider with relatively small Medicare billings will be less disadvantaged by payment adjustments than one with relatively large Medicare billings. Another uncertainty arises because there are likely to be ''bandwagon'' effects as the number of providers using EHRs rises, thereby inducing more participation in the incentives program, as well as greater adoption by entities (for example, clinical laboratories) that are not eligible for incentives or subject to payment adjustments, but do business with EHR adopters. It is impossible to predict exactly if and when such effects may take hold.

One legislative uncertainty arises because under current law, physicians are scheduled for payment reductions under the sustainable growth rate (SGR) formula for determining Medicare payments. The current override of SGR payment reductions prevents any further reductions of Medicare physician payments throughout the rest of 2012. Any payment reductions implemented in CY 2013 and subsequent calendar years could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is exceptionally uncertain. Under a current law scenario, the EHR incentives or payment adjustments would exert only a minor influence on physician behavior relative to any large payment reductions. However, the Congress has legislatively avoided physician payment reductions for each year since 2002.

All of these factors taken together make it impossible to predict with precision the timing or rates of adoption and ultimately meaningful use. Further, little new data is currently available regarding rates of adoption or costs of implementation since the publication of our Stage 1 final rule. Because of this continued uncertainty and because there is little new data on which to base alternate forecasts, we are maintaining the high and low estimates for adoption rates that we established in our Stage 1 final rule (75 FR 44548 through 44563). Therefore, we show two scenarios, which illustrate how different scenarios would impact overall costs. Our high scenario of meaningful use demonstration assumes that by 2019, nearly 100 percent of hospitals and 70 percent of EPs will be meaningful users. This estimate is based on the substantial economic incentives created by the combined direct and indirect factors affecting providers. To emphasize the uncertainties involved, we have also created a low scenario estimate for the demonstration of meaningful use each year, which assumes less robust adoption and meaningful use. Our low scenario of meaningful use

demonstration assumes that by 2019, nearly 95.6 percent of hospitals and 36 percent of EPs will be meaningful users.

Data from the EHR Incentive Program to date has shown that about 4 percent of EPs and 8 percent of hospitals received incentive payments in the first year. This may be because providers have taken a ''wait and see approach'' in the first year of implementation or that they have had problems receiving certified systems. 2011 was the first year of the program and saw initially slow, but rapidly accelerating, growth in qualification for and payment of meaningful use incentives. Given that this is very early data, and given the differences between stage 1 and stage 2 requirements, this data is not very useful in estimating penetration rates when stage 2 is implemented.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers between 2014 and 2019 to be $3.3 billion under the low scenario, and $12.7 billion under the high scenario (these estimates include net payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and beyond in the amount of $3.9 billion under the high scenario and $8.1 billion under the low scenario). We have also estimated ''per entity'' costs for EPs, eligible hospitals, and CAHs for implementation/maintenance and reporting requirement costs, not all costs. We believe also that adopting entities will achieve dollar savings at least equal to their total costs, and that there will be additional benefits to society. We believe that implementation costs are significant for each participating entity because providers who would like to qualify as meaningful users of EHRs will need to purchase certified EHR technology. However, we believe that providers who have already purchased certified EHR technology and participated in Stage 1 of meaningful use will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs to demonstrate meaningful use of certified EHR technology are outweighed by the long-term benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, the RIA that we have prepared to the best of our ability presents the costs and benefits of this proposed rule.

C. Anticipated Effects

The objective of the remainder of this RIA is to summarize the costs and benefits of the HITECH Act incentive program for the Medicare FFS, Medicaid, and MA programs. We also provide assumptions and a narrative addressing the potential costs to the industry for implementation of this technology.

1. Overall Effects

a. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the healthcare sector, Small Business Administration (SBA) size standards define a small entity as one with between $7 million and $34 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size. Individuals and States are not included in the definition of a small entity. Since the vast majority of Medicare providers (well over 90 percent) are small entities within the RFA's definitions, it is the normal practice of HHS simply to assume that all affected providers are ''small'' under the RFA. In this case, most EPs, eligible hospitals, and CAHs are either nonprofit or meet the SBA's size standard for small business. We also believe that the effects of the incentives program on many and probably most of these affected entities will be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Initial Regulatory Flexibility Analysis. We believe that the adoption and meaningful use of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some EPs and hospitals affiliated with MA organizations. While the program is voluntary, in the first 5 years it carries substantial positive incentives that will make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology for an applicable reporting period will be subject to significant Medicare payment reductions beginning with 2015. The anticipation of these Medicare payment adjustments are expected to motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs, CAHs and eligible hospitals the EHR technology they currently have could be upgraded to meet the criteria for certified EHR technology as defined for this program. These costs may be minimal, involving no more than a software upgrade. ''Home-grown'' EHR systems that might exist may also require an upgrade to meet the certification requirements. We believe many currently non-certified EHR systems will require significant changes to achieve certification and that EPs, CAHs, and eligible hospitals will have to make process changes to achieve meaningful use.

The most recent data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. A 2011 survey conducted by the Office of the National Coordinator for Health IT (ONC) and the American Hospital Association (AHA) found that the percentage of U.S. hospitals which had adopted EHRs doubled from 16 to 35 percent between 2009 and 2011. In November 2011, a Centers for Disease Control and Prevention (CDC) survey found the percentage of physicians who adopted basic electronic health records (EHRs) in their practice had doubled from 17 to 34 percent between 2008 and 2011, with the percent of primary care doctors using this technology nearly doubling from 20 to 39 percent. While these numbers are encouraging, they are still low relative to the overall population of providers. The majority of EPs still need to purchase certified EHR technology, implement this new technology, and train their staff on its use. The costs for implementation and complying with the criteria of meaningful use could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency will compensate for the initial expenditures.

(1) Number of Small Entities

In total, we estimate that there are approximately 624,000 healthcare organizations (EPs, practices, eligible hospitals or CAHs) that will be affected by the incentive program. These include hospitals and physician practices as well as doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry or a chiropractor. Additionally, as many as 45,000 nonphysician practitioners (such as certified nurse-midwives, etc) will be eligible to receive the Medicaid incentive payments.

Of the 624,000 healthcare organizations we estimate will be affected by the incentive program, we estimate that 94.71 percent will be EPs, 0.8 percent will be hospitals, and 4.47 percent will be MAO physicians or

hospitals. We further estimate that EPs will spend approximately $54,000 to purchase and implement a certified EHR and $10,000 annually for ongoing maintenance according to the CBO. In the paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, recognized the complicating factors of EHR types, available features and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of $25,000 to $45,000 per physician. For all eligible hospitals, the range is from $1 million to $100 million. Though reports vary widely, we anticipate that the average would be $5 million to achieve meaningful use. We estimate $1 million for maintenance, upgrades, and training each year.

(2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers, quite apart from the incentive payments to be provided under this rule. While economically significant, we do not believe that the net effect on individual providers will be negative over time except in very rare cases. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this rule.

b. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a RIA if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they may be subject to adjusted Medicare payments in 2015 if they fail to adopt certified EHR technology by the applicable reporting period. As stated previously, we have determined that this proposed rule would create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of certified EHR technology in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors. However, we have statutory authority to make case-by-case exceptions for significant hardship, and have proposed certain case-by-case applications that may be made when there are barriers to internet connectivity that would impact health information exchange.

c. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from— (1) imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

This rule imposes no substantial mandates on States. This program is voluntary for States and States offer the incentives at their option. The State role in the incentive program is essentially to administer the Medicaid incentive program. While this entails certain procedural responsibilities, these do not involve substantial State expense. In general, each State Medicaid Agency that participates in the incentive program will be required to invest in systems and technology to comply. States will have to identify and educate providers, evaluate their attestations and pay the incentive. However, the Federal government will fund 90 percent of the State's related administrative costs, providing controls on the total State outlay.

The investments needed to meet the meaningful use standards and obtain incentive funding are voluntary, and hence not ''mandates'' within the meaning of the statute. However, the potential reductions in Medicare reimbursement beginning with FY 2015 will have a negative impact on providers that fail to meaningfully use certified EHR technology for the applicable reporting period. We note that we have no discretion as to the amount of those potential payment reductions. Private sector EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed $136 million; however, because EPs may choose for various reasons not to participate in the program, we do not have firm data for the percentage of participation within the private sector. This RIA, taken together with the remainder of the preamble, constitutes the analysis required by UMRA.

d. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would not have a substantial direct effect on State or local governments, preempt State law, or otherwise have a Federalism implication. Importantly, State Medicaid agencies are receiving 100 percent match from the Federal government for incentives paid and a 90 percent match for expenses associated with administering the program. As previously stated, we believe that State administrative costs are minimal. We note that this proposed rule does add a new business requirement for States, because of the existing systems that will need to be modified to track and report on the new meaningful use requirements for provider attestations. We are providing 90 percent FFP to States for modifying their existing EHR Incentive Program systems. We believe the Federal share of the 90 percent match will protect the States from burdensome financial outlays and, as noted previously, States offer the Medicaid EHR incentive program at their option.

2. Effects on Eligible Professionals, Eligible Hospitals, and CAHs

a. Background and Assumptions

The principal costs of this proposed rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt, implement or upgrade and/or demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so. The estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are somewhat uncertain for several reasons: (1) The program is voluntary although payment adjustments will be imposed on Medicare providers beginning in 2015 if they are unable to demonstrate meaningful use for the applicable reporting period; (2) the criteria for the demonstration of meaningful use of certified EHR technology has been

finalized for stage 1 and is being proposed for stage 2, but will change in stage 3 and over time; and (3) the impact of the financial incentives and payment adjustments on the rate of adoption of certified EHR technology by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected. The net costs and savings shown for this program represent a possible scenario and actual impacts could differ substantially.

Based on input from a number of internal and external sources, including the Government Accountability Office (GAO) and CBO, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 570,300 Medicare FFS EPs in 2014 (some of whom will also be Medicaid EPs).
- About 14 percent of the total EPs are hospital-based Medicare EPs, and are not eligible for the program. This leaves approximately 491,000 non-hospital-based Medicare EPs in 2014.
- About 20 percent of the nonhospital-based Medicare EPs (approximately 98,200 Medicare EPs in 2014) are *also* eligible for Medicaid (meet the 30 percent Medicaid patient volume criteria), but can only be paid under one program. We assume that any EP in this situation will choose to receive the Medicaid incentive payment, because it is larger.
- About 46,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners and physicians assistants) will be eligible to receive the Medicaid incentive payments.
- 4,993 eligible hospitals comprised of the following:
  - ++ 3,573 acute care hospitals.
  - ++ 1,325 CAHs
  - ++ 84 children's hospitals (Medicaid only).
  - ++ 11 cancer hospitals (Medicaid only).
- All eligible hospitals, except for children's and cancer hospitals, may qualify and apply for both Medicare and Medicaid incentive payments.
- 12 MA organizations (about 28,000 EPs, and 29 hospitals) would be eligible for incentive payments.

b. Industry Costs and Adoption Rates

In the Stage 1 final rule (75 FR 44545 through 44547), we estimated the impact on healthcare providers using information from the same four studies cited previously in this proposed rule. Based on these studies and current average costs for available certified EHR technology products, we continue to estimate for EPs that the average adopt/implement/upgrade cost is $54,000 per physician FTE, while annual maintenance costs average $10,000 per physician FTE.

For all eligible hospitals, the range is from $1 million to $100 million. Although reports vary widely, we anticipate that the average would be $5 million to achieve meaningful use, because providers who would like to qualify as meaningful users of EHRs will need to purchase certified EHRs. We further acknowledge that ''certified EHRs'' may differ in many important respects from the EHRs currently in use and may differ in the functionalities they contain. We estimate $1 million for maintenance, upgrades, and training each year. Both of these estimates are based on average figures provided in the 2008 CBO report. Industry costs are important, in part, because EHR adoption rates will be a function of these industry costs and the extent to which the costs of ''certified EHRs'' are higher than the total value of EHR incentive payments available to EPs and eligible hospitals (as well as adjustments, in the case of the Medicare EHR incentive program) and any perceived benefits including societal benefits. Because of the uncertainties surrounding industry cost estimates, we have made various assumptions about adoption rates in the following analysis in order to estimate the budgetary impact on the Medicare and Medicaid programs.

c. Costs of EHR Adoption for EPs

Since the publication of the Stage 1 final rule, there has been little data published regarding the cost of EHR adoption and implementation. A 2011 study (*http://content.healthaffairs.org/content/30/3/481.abstract*) estimated costs of implementation for a five-physician practice to be $162,000, with $85,500 in maintenance expenses in the first year. These estimates are similar to estimates made in the Stage 1 final rule. In the absence of additional data regarding the cost of adoption and implementation costs for certified EHR technology, we propose to continue to estimate for EPs that the average adopt/implement/upgrade cost is $54,000 per physician FTE, while annual maintenance costs average $10,000 per physician FTE, based on the cost estimate of the Stage 1 final rule.

d. Costs of EHR Adoption for Eligible Hospitals

The American Hospital Association (AHA) conducts annual surveys that among other measures, track hospital spending. This data reflects the latest figures from the 2008 AHA Survey. Costs at these levels of adoption were significantly higher in 2008 than in previous years. This may better reflect the costs of implementing additional functionalities. The range in yearly information technology spending among hospitals is large, from $36,000 to over $32 million based on the AHA data. EHR system costs specifically were reported by experts to run as high as $20 million to $100 million; HHS discussions with experts led to cost ranges for adoption that varied by hospital size and level of EHR system sophistication. Research to date has shown that adoption of comprehensive EHR systems is limited. In the aforementioned AHA study, 1.5 percent of these organizations had comprehensive systems, which were defined as hospital-wide clinical documentation of cases, test results, prescription and test ordering, plus support for decision-making that included treatment guidelines. Some 10.9 percent have a basic system that does not include physician and nursing notes, and can only be used in one area of the hospital. Applying a similar standard to the 2008 AHA data, results in roughly 3 to 4 percent of hospitals having comprehensive systems and 12 to 13 percent having basic systems. According to hospital CEOs, the main barrier to adoption is the cost of the systems, and the lack of capital. Hospitals have been concerned that they will not be able to recoup their investment, and they are already operating on the smallest of margins. Because uptake of advanced systems is low, it is difficult to get a solid average estimate for implementation and maintenance costs that can be applied across the industry. In addition, we recognize that there are additional industry costs associated with adoption and implementation of EHR technology that are not captured in our estimates that eligible entities will incur. Because the impact of those activities, such as reduced staff productivity related to learning how to use the EHR technology, the need to add additional staff to work with HIT issues, administrative costs related to reporting, and the like are unknown at this time and difficult to quantify.

4. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

We propose to continue the method of cost estimation we used to determine the estimated costs of the Medicare incentives for EPs in our Stage 1 final rule (75 FR 44549). In order to

determine estimated costs, we first needed to determine the EPs with Medicare claims. Then, we calculated that about 14 percent of those EPs are hospital-based according to the definition in § 495.4 (finalized in our Stage 1 final rule), and therefore, do not qualify for incentive payments. This percent of EPs was subtracted from the total number of EPs who have claims with Medicare. These numbers were tabulated from Medicare claims data.

In the Stage 1 final rule, we also estimated that about 20 percent of EPs that were not hospital-based would qualify for Medicaid incentive payments and would choose that program because the payments are higher. Current program data does not provide additional evidence regarding this, so we continued to use the 20 percent estimation in the current projections. Of the remaining EPs, we estimated the percentage which will be meaningful users each calendar year. As discussed previously, our estimates for the number of EPs that will successfully demonstrate meaningful use of certified EHR technology are uncertain. The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of certified EHR technology and will qualify for incentive payments is a key, but a highly uncertain factor. Accordingly, the estimated number of nonhospital based Medicare EPs who will demonstrate meaningful use of certified EHR technology over the period CYs 2014 through 2019 is as shown in Table 19.

TABLE 19—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH AND LOW SCENARIO

	Calendar year					
	2014	2015	2016	2017	2018	2019
EPs who have claims with Medicare (thousands)	570.3	576.0	581.7	587.5	593.3	599.0
Non-Hospital Based EPs (thousands)	492.2	497.1	502.1	507.1	512.0	517.0
EPs that are both Medicare and Medicaid EPs (thousands)	98.4	99.4	100.4	101.4	102.4	103.4
Low Scenario:						
Percent of EPs who are Meaningful Users	18	21	24	28	32	36
Meaningful Users (thousands)	70.2	83.1	97.3	112.9	129.9	148.1
High Scenario:						
Percent of EPs who are Meaningful Users	49	53	58	62	66	70
Meaningful Users (thousands)	192.6	212.2	231.9	251.3	270.4	288.8

Our estimates of the incentive payment costs and payment adjustment savings are presented in Table 20. These costs reflect the Medicare and Medicaid incentive payments and payment adjustments included in 42 CFR Part 495 of our regulations. They reflect our assumptions about the proportion of EPs who will demonstrate meaningful use of certified EHR technology. These assumptions were developed based on a review of the studies presented in the Stage 1 impact analysis.

Specifically, our assumptions are based on literature estimating current rates of physician EHR adoption and rates of diffusion of EHRs and similar technologies. There are a number of studies that have attempted to measure the rate of adoption of electronic medical records (EMR) among physicians prior to the enactment of the HITECH Act (see, for example, Funky and Taylor (2005) The State and Pattern of Health Information Technology Adoption. RAND Monograph MG–409. Santa Monica: The RAND Corporation; Ford, E.W., Menachemi, N., Peterson, L.T., Huerta, T.R. (2009) ''Resistance is Futile: But it is Slowing the Pace of EHR Adoption Nonetheless'' Journal of the American Informatics Association 16(3): 274–281). More recently, there is also some data available to suggest that more providers have adopted EHR technology since the start of the EHR Incentive Programs. The 2011 ONC–AHA survey cited earlier found that the percentage of U.S. hospitals which had adopted EHRs increased from 16 to 35 percent between 2009 and 2011. In November 2011, the CDC survey cited earlier found the percentage of physicians who adopted basic electronic health records (EHRs) in their practice had doubled from 17 to 34 percent between 2008 and 2011. These survey results are in line with the estimated rate of EHR adoption presented in the Stage 1 impact analysis, but they constitute a relatively small sample on which to base new estimates. Therefore we maintain the estimates that were based on the study with the most rigorous definition, though we note again that neither the Stage 1 nor the Stage 2 meaningful use criteria are equivalent to a fully functional system as defined in this study. (DesRoches, CM, Campbell, EG, Rao, SR et al (2008) ''Electronic Health Records in Ambulatory Care-A National Survey of Physicians'' New England Journal of Medicine 359(1): 50–60. In addition, we note that the final penetration rates used in the initial estimates were developed in consensus with industry experts relying on the studies. Actual adoption trends could be different from these assumptions, given the elements of uncertainty we describe throughout this analysis.

Estimated net costs for the low scenario of the Medicare EP portion of the HITECH Act are shown in Table 20.

TABLE 20—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO

[In 2012 Billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2014	$0.6	.....	.....	$0.6
2015	0.5	−0.6	.....	−0.1
2016	0.3	−1.0	.....	−0.6

TABLE 20—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO—Continued

[In 2012 Billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	0.1	−1.4		−1.3
2018		−1.6		−1.6
2019		−1.6		−1.6

Estimated net costs for the high scenario of the Medicare EP portion of the HITECH Act are shown in Table 21.

TABLE 21—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO

[In 2012 Billions]

Fiscal year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$1.3			$1.3
2015	$1.1	−$0.4		$0.7
2016	$0.7	−$0.6		$0.1
2017	$0.3	−$0.8		−$0.5
2018		−$0.8		−$0.8
2019		−$0.8		−$0.8

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments (which are driven by discharges), comparing them to projected costs of attaining meaningful use, and then making assumptions about how rapidly hospitals would adopt given the fraction of their costs that were covered.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine the amount of Medicare incentive payments that each hospital in the country could potentially receive under the statutory formula, based on its admission numbers (total patients and Medicare patients). The total incentive payments potentially payable over a 4-year period vary significantly by hospitals' inpatient caseloads, ranging from a low of about $11,000 to a high of $12.9 million, with the median being $3.8 million. The potential Medicare incentive payments for each eligible hospital were compared with the hospital's expected cost of purchasing and operating certified EHR technology. Costs of adoption for each hospital were estimated using data from the 2008 AHA survey and IT supplement. Estimated costs varied by size of hospital and by the likely status of EHR adoption in that class of hospitals. Hospitals were grouped first by size (CAHs, non-CAH hospitals under 400 beds, and hospitals with 400 or more beds) because EHR adoption costs do vary by size: namely, larger hospitals with more diverse service offerings and large physician staffs generally implement more customized systems than smaller hospitals that might purchase off-the-shelf products. We then calculated the proportion of hospitals within each class that were at one of three levels of EHR adoption: (1) Hospitals which had already implemented relatively advanced systems that included CPOE systems for medications; (2) hospitals which had implemented more basic systems through which lab results could be shared, but not CPOE for medications; and (3) hospitals starting from a base level with neither CPOE or lab reporting. The CPOE for medication standard was chosen for this estimate because expert input indicated that the CPOE standard in the final meaningful use definition will be the hardest one for hospitals to meet. Table 21 provides these proportions.

TABLE 22—HOSPITAL IT CAPABILITIES BY HOSPITAL SIZE

Hospital size	Levels of adoption							
	Any CPOE Meds		Lab results		Neither		Total	
	Number of hospitals	Percentage	Number of hospitals	Percentage	Number of hospitals	Percentage	Number of hospitals	Percentage
CAHs	176	19	440	48	293	32	909	23
Small/Medium	817	31	1,352	51	462	18	2,631	67
Large (400+beds)	216	54	163	41	18	5	397	10
Total	1209	31	1955	50	773	20	3,937	100

We then calculated the costs of moving from these stages to meaningful use for each class of hospital, assuming that even for hospitals with CPOE systems they would incur additional costs of at least 10 percent of their IT budgets. These costs were based on cross-sectional data from the AHA survey and thus do not likely represent the true costs of implementing systems. This data reflects the latest figures from the 2008 AHA Survey. Costs at these levels of adoption were significantly higher than in previous years. This may better reflect the costs of implementing additional functionalities. We have also updated the number of discharges using the most recent cost report data available. The payment incentives available to hospitals under the Medicare and Medicaid programs are included in our regulations at 42 CFR part 495. We estimate that there are 12 MAOs that might be eligible to participate in the incentive program. Those plans have 29 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

Our high scenario estimated net costs for section 4102 of the HITECH Act are shown in Table 23: Estimated costs (+) and savings (–) for eligible hospitals adopting certified EHRs. This provision is estimated to increase Medicare hospital expenditures by a net total of $5.4 billion during FYs 2014 through 2019.

TABLE 23—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO

[In 2012 billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2014	$1.9	.....	(1)	$1.9
2015	2.1	−0.3	(1)	1.8
2016	1.3	−0.1	(1)	1.2
2017	0.5	−0.1	(1)	0.5
2018	.....	(1)	(1)	(1)
2019	.....	.....	(1)	(1)

[1] Savings of less than $50 million.

We are also providing the estimates for a low scenario in Table 24.

TABLE 24—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO

[In 2012 billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2014	$1.2	.....	(1)	$1.2
2015	1.4	−0.9	(1)	0.5
2016	1.2	−0.6	(1)	0.6
2017	0.6	−0.3	(1)	0.3
2018	.....	−0.2	(1)	−0.2
2019	.....	−0.1	(1)	−0.1

[1] Savings of less than $50 million.

Based on the comparison of Medicare incentive payments and implementation/operating costs for each eligible hospital (described previously), we made the assumptions shown in Tables 25 and 26, related to the prevalence of certified EHR technology for FYs 2014 through 2018. These assumptions are consistent with the actual program data for 2011. As indicated, eligible hospitals that could cover the full cost of an EHR system through Medicare incentive payments were assumed to implement them relatively rapidly, and vice versa. In other words, eligible hospitals will have an incentive to purchase and implement an EHR system if they perceive that a large portion of the costs will be covered by the incentive payments. Table 25 shows the scenario's estimates:

TABLE 25—ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS HIGH SCENARIO

Fiscal year	Incentive payments as percentage of EHR technology cost				
	100+%	75–100%	50–75%	25–50%	0–25%
2014	1.0	0.95	0.85	0.75	0.6
2015	1.0	1.0	0.95	0.9	0.8
2016	1.0	1.0	1.0	0.95	0.9
2017	1.0	1.0	1.0	1.0	0.95

TABLE 25—ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS HIGH SCENARIO—Continued

Fiscal year	Incentive payments as percentage of EHR technology cost				
	100+%	75–100%	50–75%	25–50%	0–25%
2018	1.0	1.0	1.0	1.0	1.0

For instance, under the high scenario 95 percent of eligible hospitals whose incentive payments would cover between 75 percent and 100 percent of the cost of a certified EHR system were assumed to have a certified system in FY 2014. All such hospitals were assumed to have a certified EHR system in FY 2015 and thereafter.

High rates of EHR adoption are anticipated in the years leading up to FY 2015 due to the payment adjustments that will be imposed on eligible hospitals. However, we know from industry experts that issues surrounding the capacity of vendors and expert consultants to support implementation, issues of access to capital, and competing priorities in responding to payer demand will limit the number of hospitals that can adopt advanced systems in the short-term. Therefore, we cannot be certain of the adoption rate for hospitals due to these factors and others previously outlined in this preamble.

Table 26 shows the low scenario estimates.

TABLE 26—ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS LOW SCENARIO

Fiscal year	Incentive payments as percentage of EHR technology cost				
	100+%	75–100%	50–75%	25–50%	0–25%
2014	0.9	0.75	0.55	0.4	0.3
2015	1.0	0.9	0.75	0.6	0.5
2016	1.0	1.0	0.9	0.85	0.75
2017	1.0	1.0	0.95	0.9	0.85
2018	1.0	1.0	1.0	0.95	0.9
2019	1.0	1.0	1.0	1.0	1.0

For large, organized facilities such as hospitals, we believe that the revenue losses caused by these payment adjustments would be a substantial incentive to adopt certified EHR technology, even in instances where the Medicare incentive payments would cover only a portion of the costs of purchasing, installing, populating, and operating the EHR system. Based on the assumptions about incentive payments as percentages of EHR technology costs in Table 27, we estimated that the great majority of eligible hospitals would qualify for at least a portion of the Medicare incentive payments that they could potentially receive, and only a modest number would incur payment adjustments. Nearly all eligible hospitals are projected to have implemented certified EHR technology by FY 2019. Table 27 shows our high scenario estimated percentages of the total potential incentive payments associated with eligible hospitals that could demonstrate meaningful use of EHR systems. Also shown are the estimated percentages of potential incentives that would actually be paid each year.

TABLE 27—ESTIMATED PERCENTAGE OF MEDICARE INCENTIVES WHICH COULD BE PAID FOR MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE IN YEAR, HIGH SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2014	82.6	82.6
2015	92.6	54.2
2016	96.9	43.4
2017	99.0	.....
2018	100.0	.....

For instance in FY 2014 under the high scenario, 82.6 percent of the total amount of incentive payments which could be payable in that year would be for eligible hospitals who have demonstrated meaningful use of certified EHR technology and therefore will be paid. In FY 2015 under the high scenario, 92.6 percent of the total amount of incentive payments which could be payable will be for hospitals who have certified EHR systems, but some of those eligible hospitals would have already received 4 years of incentive payments, and therefore 54.2 percent of all possible incentive payments actually paid in that year.

Table 28 shows the low scenario estimates.

TABLE 28—ESTIMATED PERCENTAGE OF MEDICARE INCENTIVES WHICH COULD BE PAID FOR THE MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE IN YEAR, LOW SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2014	47.6	47.6
2015	66.4	49.6
2016	85.9	64.1
2017	91.4	.....
2018	95.6	.....

The estimated payments to eligible hospitals were calculated based on the hospitals' qualifying status and individual incentive amounts under the statutory formula. Similarly, the estimated payment adjustments for nonqualifying hospitals were based on the market basket reductions and Medicare revenues. The estimated savings in Medicare eligible hospital benefit expenditures resulting from the use of hospital certified EHR systems are discussed under ''general considerations'' at the end of this section. We assumed no future growth in the total number of hospitals in the U.S. because growth in acute care hospitals has been minimal in recent years.

c. Critical Access Hospitals (CAHs)

We estimate that there are 1,325 CAHs eligible to receive EHR incentive payments. In the Stage 1 impact analysis, we estimated that the 22 percent of CAHs with relatively advanced EHR systems would achieve meaningful use before 2016 given on the financial assistance available under HITECH for Regional Extension Centers, whose priorities include assisting CAHs in EHR adoption. We also estimated that most of the remaining CAHs that had already adopted some kind of EHR system at that time (51 percent of CAHs) would also achieve meaningful use by 2016. Current program payment data, as well as current data from the Regional Extension Centers, does not provide enough information for us to alter these estimates. Therefore, we are maintaining these estimates for the current impact analysis. Our estimates regarding the incentives that will be paid to CAHs are incorporated into the overall Medicare and Medicaid program costs.

5. Medicaid Incentive Program Costs

Under section 4201 of the HITECH Act, States can voluntarily participate in the Medicaid incentive payment program. However, as of the writing of this proposed rule 43 States are already participating in the Medicaid incentive payment program and the remaining States have indicated they will begin participation in 2012. Therefore we anticipate that all States will be participating by 2014, as we estimated in the Stage 1 impact analysis. The payment incentives available to EPs and hospitals under the Medicaid programs are included in our regulations at 42 CFR Part 495. The Federal costs for Medicaid incentive payments to providers who can demonstrate meaningful use of EHR technology were estimated similarly to the estimates for Medicare eligible hospital and EP. Table 29 shows our high estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 29—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (−) UNDER MEDICAID, HIGH SCENARIO

[In 2012 $billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2014	0.7	0.9	(1)	1.6
2015	0.6	1.1	(1)	1.7
2016	0.5	1.1	(1)	1.7
2017	0.4	0.9	(1)	1.3
2018	0.2	0.6	(1)	0.7
2019	0.0	0.3	(1)	0.3

[1] Savings of less than $50 million.

Table 30 shows the low estimates for Medicaid costs and savings.

TABLE 30—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (−) UNDER MEDICAID, LOW SCENARIO

[In 2012 $billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2014	0.4	0.4	(1)	0.8
2015	0.5	0.5	(1)	1.0

TABLE 30—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (−) UNDER MEDICAID, LOW SCENARIO—Continued

[In 2012 $billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2016	0.7	0.6	(1)	1.3
2017	0.8	0.5	(1)	1.3
2018	0.4	0.4	(1)	0.9
2019	0.1	0.3	(1)	0.4

[1] Savings of less than $50 million.

a. Medicaid EPs

To determine the Medicaid EP incentive payments, we first determined the number of qualifying EPs. As indicated previously, we assumed that 20 percent of the non-hospital-based Medicare EPs would meet the requirements for Medicaid incentive payments (30 percent of patient volume from Medicaid). All of these EPs were assumed to choose the Medicaid incentive payments, as they are larger. In addition, the total number of Medicaid EPs was adjusted to include EPs who qualify for the Medicaid incentive payments but not for the Medicare incentive payments, such as most pediatricians, dentists, certified nurse-midwives, nurse practitioners and physicians assistants. As noted previously, there is much uncertainty about the rates of demonstration of meaningful use that will be achieved. Our high scenario estimates are listed in Table 31.

TABLE 31—ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WILL BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO

[All population figures are in thousands]

		Calendar year					
		2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital-Based EPs	492.2	497.1	502.1	507.1	512.0	517.0
A	EPs who meet the Medicaid patient volume threshold	98.4	99.4	100.4	101.4	102.4	103.4
B	Medicaid [1] only EPs	46.3	47.1	47.8	48.6	49.3	50.1
	Total Medicaid EPs (A + B)	144.7	146.5	148.2	150.0	151.7	153.5
	Percent of EPs receiving incentive payment during year	82.2%	85.6%	88.8%	43.8%	25.0%	14.4%
	Number of EPs receiving incentive payment during year	119.0	125.4	131.7	65.7	38.0	22.1
	Percent of EPs who have ever received incentive payment	82.2%	85.6%	88.8%	91.9%	94.7%	95.9%
	Number of EPs who have ever received incentive payment	119.0	125.4	131.7	137.7	143.6	147.2

It should be noted that since the Medicaid EHR incentive payment program provides that a Medicaid EP can receive an incentive payment in their first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing certified EHR technology as well. Table 32 shows our low scenario estimates.

TABLE 32—ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WILL BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY LOW SCENARIO

[All population figures are in thousands]

		Calendar year					
		2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital-Based EPs	492.2	497.1	502.1	507.1	512.0	517.0
A	EPs who meet the Medicaid patient volume threshold	98.4	99.4	100.4	101.4	102.4	103.4
B	Medicaid [1] only EPs	46.3	47.1	47.8	48.6	49.3	50.1
	Total Medicaid EPs (A + B)	144.7	146.5	148.2	150.0	151.7	153.5
	Percent of EPs receiving incentive payment during year	36.0%	40.5%	45.3%	30.7%	21.9%	15.1%
	Number of EPs receiving incentive payment during year	52.1	59.4	67.2	46.0	33.2	23.1
	Percent of EPs who have ever received incentive payment	36.0%	40.5%	45.3%	50.4%	55.7%	59.9%
	Number of EPs who have received ever incentive payment	52.1	59.4	67.2	75.5	84.4	91.9

b. Medicaid Hospitals

Medicaid incentive payments to most acute-care hospitals were estimated using the same adoption assumptions and method as described previously for Medicare eligible hospitals and shown in Table 33. Because hospitals' Medicare and Medicaid patient loads differ, we separately calculated the range of percentage of total potential incentives that could be associated with qualifying hospitals, year by year, and the corresponding actual percentages payable each year. Acute care hospitals may qualify to receive both the Medicare and Medicaid incentive payments.

As stated previously, the estimated eligible hospital incentive payments were calculated based on the hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The estimated savings in Medicaid benefit expenditures resulting from the use of certified EHR technology are discussed under ''general considerations.'' Since we were using Medicare cost report data and little data existed for children's hospitals, we estimated the Medicaid incentives payable to children's hospitals as an add-on to the base estimate, using data on the number of children's hospitals compared to non-children's hospitals.

TABLE 33—ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR, HIGH SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2014	83.1	44.0
2015	92.9	38.5
2016	97.1	26.2
2017	99.0	14.0
2018	100.0	4.2
2019	100.0	0.0

Table 34 shows our low scenario estimates.

TABLE 34—ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR, LOW SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2014	49.2	30.9
2015	67.8	44.5
2016	86.5	52.8
2017	91.8	37.3
2018	95.9	18.7
2019	100.0	0.0

6. Benefits for All EPs and All Eligible Hospitals

In this proposed rule we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin *et al.* 2011 ''The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results'' *Health Affairs*.) found that 92 percent of articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key aspects of care, including quality and efficiency of health care. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. Another study, at one hospital emergency room in Delaware, showed the ability to download and create a file with a patient's medical history saved the ER $545 per use, mostly in reduced waiting times. A pilot study of ambulatory practices found a positive ROI within 16 months and annual savings thereafter (Greiger *et al.* 2007, A Pilot Study to Document the Return on Investment for Implementing an Ambulatory Electronic Health Record at an Academic Medical Center *http://www.journalacs.org/article/S1072-7515%2807%2900390-0/abstract-article-footnote-1s*.) A study that compared the productivity of 75 providers within a large urban primary care practice over a four year period showed increases in productivity of 1.7 percent per month per provider after EHR adoption (DeLeon *et al.* 2010, ''The business end of health information technology. Can a fully integrated electronic health record increase provider productivity in a large community practice?'' *J Med Pract Manage*). Some vendors have estimated that EHRs could result in cost savings of between $100 and $200 per patient per year. At the time of the writing of this proposed rule, there was only limited information on participation in the EHR Incentive Programs and on adoption of Certified EHR Technology. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and

benefits. A number of relevant studies are required in the HITECH Act for this specific purpose, and the results will be made public, as they are available.

7. Benefits to Society

According to the recent CBO study ''Evidence on the Costs and Benefits of Health Information Technology'' (*http://www.cbo.gov//ftpdocs/91xx/doc9168/05-20-HealthIT.pdf*) when used effectively, EHRs can enable providers to deliver health care more efficiently. For example, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care reduce unnecessary office visits and assist in managing complex care. This is consistent with the findings in the ONC study cited previously. Further, the CBO report claims that there is a potential to gain both internal and external savings from widespread adoption of health IT, noting that internal savings would likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the ability to exchange information more efficiently. However, it is important to note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a potential area of research and analysis that remains unexamined. The benefits resulting specifically from this proposed regulation are even harder to quantify because they represent, in many cases, adding functionality to existing systems and reaping the network externalities created by larger numbers of providers participating in information exchange.

Since the CBO study, there has been additional research that has emerged documenting the association of EHRs with improved outcomes among diabetics (Hunt, JS *et al.* (2009) ''The impact of a physician-directed health information technology system on diabetes outcomes in primary care: a pre- and post-implementation study'' Informatics in Primary Care 17(3):165–74; Pollard, C *et al.* (2009) ''Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers'' Journal of Rural Health 25(1):77–84) and trauma patients (Deckelbaum, D. *et al.* (2009) ''Electronic medical records and mortality in trauma patients ''The Journal of Trauma: Injury, Infection, and Critical Care 67(3): 634–636), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) ''The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care.''Health Affairs 28(2):323–333), and improved outcomes and lower costs in hospitals (Amarasingham, R. *et al.* (2009) ''Clinical information technologies and inpatient outcomes: a multiple hospital study'' Archives of Internal Medicine 169(2):108–14). However, data relating specifically to the EHR Incentive Programs is limited at this time.

8. General Considerations

The estimates for the HITECH Act provisions were based on the economic assumptions underlying the President's 2013 Budget. Under the statute, Medicare incentive payments for certified EHR technology are excluded from the determination of MA capitation benchmarks. As noted previously, there is considerable uncertainty about the rate at which eligible hospitals, CAHs and EPs are adopting EHRs and other HIT. Nonetheless, we believe that the Medicare incentive payments and the prospect of significant payment adjustments for not demonstrating meaningful use will result in the great majority of hospitals implementing certified EHR technology in the early years of the Medicare EHR incentive program. We expect that a steadily growing proportion of practices will implement certified EHR technology over the next 10 years, even in the absence of the Medicare incentives. Actual future Medicare and Medicaid costs for eligible hospital and EP incentives will depend in part on the standards developed and applied for assessing meaningful use of certified EHR technology. We are administering the requirements in such a way as to encourage adoption of certified EHR technology and facilitate qualification for incentive payments, and expect to adopt progressively demanding standards at each stage year. Certified EHR technology has the potential to help reduce medical costs through efficiency improvements, such as prompter treatments, avoidance of duplicate or otherwise unnecessary services, and reduced administrative costs (once systems are in place), with most of these savings being realized by the providers rather than by Medicare or Medicaid. To the extent that this technology will have a net positive effect on efficiency, then more rapid adoption of such EHR systems would achieve these efficiencies sooner than would otherwise occur, without the EHR incentives. We expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid as a result of the implementation of EHR technology.

In the process of preparing the estimates for this rule, we consulted with and/or relied on internal CMS sources, as well as the following sources:

- Congressional Budget Office (staff and publications).
- American Medical Association (staff and unpublished data).
- American Hospital Association.
- Actuarial Research Corporation.
- CMS Statistics 2011.
- RAND Health studies on:

++ ''The State and Pattern of Health Information Technology Adoption'' (Fonkych & Taylor, 2005);

++ ''Extrapolating Evidence of Health Information Technology Savings and Costs'' (Girosi, Meili, & Scoville, 2005); and

++ ''The Diffusion and Value of Healthcare Information Technology'' (Bower, 2005).

- Kaiser Permanente (staff and publications).
- Miscellaneous other sources (Health Affairs, American Enterprise Institute, ONC survey, Journal of Medical Practice Management, news articles and perspectives).

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the HITECH Act with much certainty. We believe the assumptions and methods described herein are reasonable for estimating the financial impact of the provisions on the Medicare and Medicaid programs, but acknowledge the wide range of possible outcomes.

9. Summary

Consistent with the estimates we are maintaining from the Stage 1 final rule, the total cost to the Medicare and Medicaid programs between 2014 and 2019 is estimated to be $3.3 billion in transfers under the low scenario, and $12.7 billion under the high scenario. We do not estimate total costs to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance.

TABLE 35—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)—(IN 2012 BILLIONS) LOW SCENARIO

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2014	$1.2	$0.6	$0.4	$0.4	$2.6
2015	0.5	−0.1	0.5	0.5	1.4
2016	0.6	−0.6	0.7	0.6	1.3
2017	0.3	−1.3	0.8	0.5	0.3
2018	−0.2	−1.6	0.4	0.4	−1.0
2019	−0.1	−1.6	0.1	0.3	−1.3

Table 36 shows the total costs from 2014 through 2019 for the high scenario.

TABLE 36—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)—(IN 2012 BILLIONS) HIGH SCENARIO

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2014	$1.9	$1.3	$0.7	$0.9	$4.8
2015	1.8	0.7	0.6	1.1	4.2
2016	1.2	0.1	0.5	1.1	2.9
2017	0.5	−0.5	0.4	0.9	1.3
2018	.....	−0.8	0.2	0.6	0.0
2019	.....	−0.8	.....	0.3	−0.5

10. Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits to the program would accrue in the form of savings to Medicare, through the Medicare EP payment adjustments. Expected qualitative benefits, such as improved quality of care, better health outcomes, and the like, are unable to be quantified at this time.

D. Accounting Statement

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized benefits and nonbudgetary costs are presented as discounted flows using 3 percent and 7 percent factors. Additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt and demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so are noted by a placeholder in the accounting statement. We are not able to explicitly define the universe of those additional costs, nor specify what the high or low range might be to implement EHR technology in this proposed rule.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities such as temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting.

TABLE 37—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYS 2014 THROUGH 2019

[In 2012 millions]

Category	Benefits				
Qualitative	Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like.				
	Costs				
	Year dollar	Estimates (in millions)		Unit discount rate	Period covered
		Low estimate	High estimate		
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements.	2012	$186.5	$191.8	7%	CYs 2014–2019
		$186.5	$191.8	3%	

TABLE 37—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYS 2014 THROUGH 2019—Continued

[In 2012 millions]

Qualitative—Other private industry costs associated with the adoption of EHR technology.	These costs would include the impact of EHR activities such as reduced staff productivity related to learning how to use the EHR technology, the need for additional staff to work with HIT issues, and administrative costs related to reporting.				
	Transfers				
	Year dollar	Estimates (in millions)		Unit discount rate	Period covered
		Low estimate	High estimate		
Federal Annualized Monetized	2012	$705.7	$2,345.6	7%	CYs 2014–2019
		$618.2	$2,216.9	3%	
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals.				

E. Conclusion

The previous analysis, together with the remainder of this preamble, provides an RIA. We believe there are many positive effects of adopting EHR on health care providers, quite apart from the incentive payments to be provided under this rule. We believe there are benefits that can be obtained by eligible hospitals and EPs, including: Reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, and reduced errors. When used effectively, EHRs can enable providers to deliver health care more efficiently. For example, EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits and assist in managing complex care. We also believe that internal savings would likely come through the reductions in the cost of providing care. While economically significant, we do not believe that the net effect on individual providers will be negative over time except in very rare cases. Accordingly, we believe that the object of the Regulatory Flexibility Analysis to minimize burden on small entities are met by this proposed rule. We invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart D—Basic Method for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

2. Section 412.64 is amended as follows:

A. Revising paragraph (d)(3) introductory text.

B. Adding paragraphs (d)(4) and (d)(5).

The revision and addition read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(3) Beginning in fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the applicable percentage change specified in paragraph (d)(1) of this section is reduced—

* * * * *

(4) *Exception*—(i) *General rules.* The Secretary may, on a case-by-case basis, exempt an eligible hospital that is not a qualifying eligible hospital from the application of the reduction under paragraph (d)(3) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the eligible hospital.

(ii) To be considered for an exception, a hospital must submit an application, in the manner specified by CMS, demonstrating that it meets one or more than one of the criteria specified in this paragraph (d). Such exceptions are subject to annual renewal, but in no case may a hospital be granted such an exception for more than 5 years. (See § 495.4 for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.)

(A) During the fiscal year that is 2 years before the payment adjustment year, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted no later than April 1 of the year before the applicable payment adjustment year.

(B) During either of the 2 fiscal years before the payment adjustment year, the hospital faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted no later than April 1 of the year before the applicable payment adjustment year.

(C) The hospital is new in the payment adjustment year, and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period as a new hospital. For purposes of this exception, the following hospitals are not considered new hospitals:

(*1*) A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(*2*) A hospital that closes and subsequently reopens.

(*3*) A hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.

(*4*) A hospital that changes its status from a CAH to a hospital that is subject to the capital prospective payment systems.

(5) A State in which hospitals are paid for services under section 1814(b)(3) of the Act must adjust the payments to each eligible hospital in the State that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction under paragraph (d)(3) of this section. Such a State must provide to the Secretary, no later than January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

4. Section 413.70 is amended by revising paragraphs (a)(6)(i) introductory text, (a)(6)(ii), and (a)(6)(iii) to read as follows:

§ 413.70 Payment for services of a CAH.

(a) * * *

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH for the applicable EHR reporting period, as defined in § 495.4 and § 495.106(a) of this chapter, then notwithstanding the percentage applicable in paragraph (a)(1) of this section, the reasonable costs of the CAH in providing CAH services to its inpatients are adjusted by the following applicable percentage:

* * * * *

(ii) The Secretary may on a case-by-case basis, exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful user would result in a significant hardship for the CAH. In order to be considered for an exception, a CAH must submit an application demonstrating that it meets one or more of the criteria specified in this paragraph (a) for the applicable payment adjustment year no later than 60 days after the close of the applicable EHR reporting period. The Secretary may grant an exception for one or more than one of the following:

(A) A CAH that is located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity and faced insurmountable barriers to obtaining such internet connectivity.

(B) A CAH that faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user.

(C) A new CAH, which, for the purposes of this exception, means a CAH that has operated (under previous or present ownership) for less than 1 year. This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period as a new CAH. For the purposes of this exception, the following CAHs are not considered new CAHs:

(*1*) A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(*2*) A CAH that closes and subsequently reopens.

(*3*) A CAH that has been in operation for more than 1 year but has participated in the Medicare program for less than 1 year.

(*4*) A CAH that has been converted from an eligible hospital as defined at § 495.4 of this chapter.

(iii) Exceptions granted under paragraph (a)(6)(ii) of this section are subject to annual renewal, but in no case may a CAH be granted such an exception for more than 5 years.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

5. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

6. Section 495.4 is amended as follows:

A. Revising the definition of ''EHR reporting period''.

B. Adding the definition of ''EHR reporting period for a payment adjustment year'' in alphabetical order.

C. Revising the definition of ''Hospital-based EP,'' and paragraphs (1) and (3) of the definition of ''Meaningful EHR user''.

D. Adding the definition of ''Payment adjustment year'' in alphabetical order.

The additions and revisions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. Except with respect to payment adjustment years, EHR reporting period means either of the following:

(1) For an eligible EP—

(i) For the payment year in which the EP is first demonstrating he or she is a

meaningful EHR user, any continuous 90-day period within the calendar year;

(ii) For the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(2) For an eligible hospital or CAH—

(i) For the payment year in which the eligible hospital or CAH is first demonstrating it is a meaningful EHR user, any continuous 90-day period within the Federal fiscal year;

(ii) For the subsequent payment years following the payment year in which the eligible hospital or CAH first successfully demonstrates it is a meaningful EHR user, the Federal fiscal year.

EHR reporting period for a payment adjustment year. For a payment adjustment year, the EHR reporting period means the following:

(1) For an EP—

(i) Except as provided in paragraphs (1)(ii) and (iii) of this definition, the calendar year that is 2 years before the payment adjustment year.

(ii) If an EP is demonstrating he or she is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, then any continuous 90-day period within such (2 years prior) calendar year.

(iii)(A) If in the calendar year that is 2 years before the payment adjustment year and in all prior calendar years, the EP has not successfully demonstrated he or she is a meaningful EHR user, then any continuous 90-day period that both begins in the calendar year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year.

(B) Under this exception, the provider must successfully register for and attest to meaningful use no later than the date October 1 of the year before the payment adjustment year.

(2) For an eligible hospital—

(i) Except as provided in paragraphs (2)(ii) and (iii) of this definition, the Federal fiscal year that is 2 years before the payment adjustment year.

(ii) If an eligible hospital is demonstrating it is a meaningful EHR user for the first time in the Federal fiscal year that is 2 years before the payment adjustment year, then any continuous 90-day period within such (2 years prior) Federal fiscal year.

(iii)(A) If in the Federal fiscal year that is 2 years before the payment adjustment year and for all prior Federal fiscal years the eligible hospital has not successfully demonstrated it is a meaningful EHR user, then any continuous 90-day period that both begins in the Federal fiscal year that is 1 year before the payment adjustment year and ends at least 3 months before the end of such prior Federal fiscal year.

(B) Under this exception, the eligible hospital must successfully register for and attest to meaningful use no later than July 1 of the year before the payment adjustment year.

(3) For a CAH—

(i) Except as provided in paragraph (3)(ii) of this definition, the Federal fiscal year that is the payment adjustment year.

(ii) If the CAH is demonstrating it is a meaningful EHR user for the first time in the payment adjustment year, any continuous 90-day period within the Federal fiscal year that is the payment adjustment year.

* * * * *

Hospital-based EP is an EP (as defined under this section) who furnishes 90 percent or more of his or her covered professional services in a hospital setting in the year preceding the payment year, or in the year 2 years before the payment adjustment year. For Medicare, this will be calculated based on the Federal FY before the payment year for purposes of determining qualification for incentive payments, or 2 years before the or payment adjustment year for purposes of determining whether a payment adjustment applies. For Medicaid, it is at the State's discretion if the data is gathered on the Federal FY or CY before the payment year. A setting is considered a hospital setting if it is a site of service that would be identified by the codes used in the HIPAA standard transactions as an inpatient hospital, or emergency room setting.

* * * * *

Meaningful EHR user * * * (1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year, demonstrates in accordance with § 495.8 meaningful use of Certified EHR Technology by meeting the applicable objectives and associated measures under § 495.6 and successfully reporting the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable; and

* * * * *

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or during an applicable EHR reporting period for a payment adjustment year) must occur at a practice/location or practices/locations equipped with Certified EHR Technology.

* * * * *

Payment adjustment year means either of the following:

(1) For an EP, a calendar year beginning with CY 2015.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2015.

* * * * *

7. Section 495.6 is amended as follows:

A. Redesignating paragraph (a)(2)(ii) as paragraph (a)(2)(ii)(A).

B. Adding paragraph (a)(2)(ii)(B).

C. Redesignating paragraph (b)(2)(ii) as paragraph (b)(2)(ii)(A).

D. Adding paragraph (b)(2)(ii)(B).

E. Redesignating paragraph (d)(1)(ii) as paragraph (d)(1)(ii)(A).

F. Adding paragraphs (d)(1)(ii)(B) and (C).

G. Redesignating paragraph (d)(8)(i)(E) as paragraph (d)(8)(i)(E)(*1*).

H. Adding a paragraph (d)(8)(i)(E)(*2*).

I. Redesignating paragraph (d)(8)(ii) as paragraph (d)(8)(ii)(A).

J. Adding paragraphs (d)(8)(ii)(B) and (C).

K. Redesignating paragraph (d)(8)(iii) as paragraph (d)(8)(iii)(A).

L. Adding paragraphs (d)(8)(iii)(B) and (C).

M. Redesignating paragraph (d)(10)(i) as paragraph (d)(10)(i)(A).

N. Adding paragraph (d)(10)(i)(B).

O. Redesignating paragraph (d)(10)(ii) as paragraph (d)(10)(ii)(A).

P. Adding a paragraph (d)(10)(ii)(B).

Q. Redesignating paragraph (d)(12)(i) as paragraph (d)(12)(i)(A).

R. Adding a paragraph (d)(12)(i)(B).

S. Redesignating paragraph (d)(12)(ii) as paragraph (d)(12)(ii)(A).

T. Adding a paragraph (d)(12)(ii)(B).

U. Redesignating paragraph (d)(12)(iii) as paragraph (d)(12)(iii)(A).

V. Adding a paragraph (d)(12)(iii)(B).

W. Redesignating paragraph (d)(14)(i) as paragraph (d)(14)(i)(A).

X. Adding a paragraph (d)(14)(i)(B).

Y. Redesignating paragraph (d)(14)(ii) as paragraph (d)(14)(ii)(A).

Z. Adding a paragraph (d)(14)(ii)(B).

AA. In paragraph (e) introductory text—

(i) Removing the ''**:**'' and adding a ''**.**'' in its place.

(ii) Adding a sentence at the end of the paragraph.

BB. Redesignating paragraph (e)(5)(i) as paragraph (e)(5)(i)(A).

CC. Adding a paragraph (e)(5)(i)(B).

DD. Redesignating paragraph (e)(5)(ii) as paragraph (e)(5)(ii)(A).

EE. Adding paragraph (e)(5)(ii)(B).

FF. Redesignating paragraph (e)(9)(i) as (e)(9)(i)(A).

GG. Adding paragraph (e)(9)(i)(B).

HH. Redesignating paragraph (e)(10)(i) as (e)(10)(i)(A).

II. Adding paragraph (e)(10)(i)(B).

JJ. Redesignating paragraph (f)(1)(ii) as paragraph (f)(1)(ii)(A).

KK. Adding paragraphs (f)(1)(ii)(B) and (C).

LL. Redesignating paragraph (f)(7)(i)(E) as paragraph (f)(7)(i)(E)(*1*).

MM. Adding a paragraph (f)(7)(i)(E)(*2*).

NN. Redesignating paragraph (f)(7)(ii) as (f)(7)(ii)(A).

OO. Adding paragraphs (f)(7)(ii)(B) and (C).

PP. Redesignating paragraph (f)(9)(i) as paragraph (f)(9)(i)(A).

QQ. Adding a paragraph (f)(9)(i)(B).

RR. Redesignating paragraph (f)(9)(ii) as paragraph (f)(9)(ii)(A).

SS. Adding a paragraph (f)(9)(ii)(B).

TT. Redesignating paragraph (f)(12)(i) as paragraph (f)(12)(i)(A).

UU. Adding a paragraph (f)(12)(i)(B).

VV. Redesignating paragraph (f)(12)(ii) as paragraph (f)(12)(ii)(A).

WW. Adding a paragraph (f)(12)(ii)(B).

XX. Redesignating paragraph (f)(13)(i) as paragraph (f)(13)(i)(A).

YY. Adding a paragraph (f)(13)(i)(B).

ZZ. Redesignating paragraph (f)(13)(ii) as paragraph (f)(13)(ii)(A).

AAA. Adding a paragraph (f)(13)(ii)(B).

BBB. In paragraph (g) introductory text—

(i) Removing the ''**:**'' and adding a ''**.**'' in its place.

(ii) Adding a sentence at the end of the paragraph.

CCC. Redesignating paragraph (g)(8)(i) as paragraph (g)(8)(i)(A).

DDD. Adding a paragraph (g)(8)(i)(B).

EEE. Redesignating paragraph (g)(9)(i) as paragraph (g)(9)(i)(A).

FFF. Adding a paragraph (g)(9)(i)(B).

GGG Redesignating paragraph (g)(10)(i) as paragraph (g)(10)(i)(A).

HHH. Adding a paragraph (g)(10)(i)(B).

III. Revising paragraphs (h) and (i).

JJJ. Adding new paragraphs (j) through (m).

The additions and revisions read as follows:

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(B) Beginning in 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section unless five or more exclusions apply. An EP must meet five of the objectives and associated measures specified in paragraph (e) of this section, one of which must be either paragraph (e)(9) or (e)(10) of this section, unless the EP meets five or more exclusions specified in paragraph (e) of this section, in which case the EP must meet all remaining objectives and associated measures.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Beginning in 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (g) of this section. Eligible hospitals or CAHs must meet five of the objectives and associated measures specified in paragraph (g) of this section, one which must be specified in paragraph (g)(8), (g)(9), or (g)(10) of this section.

(d) * * *

(1) * * *

(ii) * * *

(B) For 2013, subject to paragraph (c) of this section, more than 30 percent of medication orders created by the EP during the EHR reporting period are recorded using CPOE or the measure specified in paragraph (d)(1)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (d)(1)(ii)(B) of this section.

* * * * *

(8)(i) * * *

(E) * * *

(*2*) For 2013, plot and display growth charts for patients 0–20 years, including BMI.

(ii) * * *

(B) For 2013—(*1*) Subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(*2*) The measure specified in paragraph (d)(8)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (d)(8)(ii)(B) of this section.

(iii) * * *

(B) For 2013, any EP who—

(*1*) Sees no patients 3 years or older is excluded from recording blood pressure;

(*2*) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(*3*) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(*4*) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(C) Beginning 2014, only exclusion in paragraph (d)(8)(iii)(B) of this section.

* * * * *

(10)(i) * * *

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in § 495.4 and is no longer listed as an objective in this paragraph (d).

(ii) * * *

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as a measure in this paragraph (d).

* * * * *

(12)(i) * * *

(B) Beginning 2014, provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

(ii) * * *

(B) Beginning 2014, subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

(iii) * * *

(B) Beginning in 2014, any EP who neither orders nor creates any of the information listed for inclusion as part of this measure.

(14)(i) * * *

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2013, this measure is no longer required as part of the core set.

* * * * *

(e) * * *. Beginning in 2014, an EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (e)(10) of this section unless the EP meets five or more exclusions specified in this paragraph (e), in which case the EP must meet all remaining objectives and associated measures:

* * * * *

(5)(i) * * *

(B) Beginning 2014, this objective is no longer included in the menu set.

(ii) * * *

(B) Beginning 2014, this measure is no longer included in the menu set.

* * * * *

(9)(i) * * *

(B) Beginning in 2013, capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(10)(i) * * *

(B) Beginning in 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(B) Beginning 2013, subject to paragraph (c) of this section, more than 30 percent of medication orders created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period are recorded using CPOE, or the measure specified in paragraph (f)(1)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (f)(1)(ii)(B) of this section.

* * * * *

(7) * * *

(i) * * *

(E) * * *

(*2*) Beginning 2013, plot and display growth charts for patients 0–20 years, including BMI.

(ii) * * *

(B) For 2013, subject to paragraph (c) of this section, more than 50 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) are recorded as structured data.

(C) Beginning 2014, only the measure specified in paragraph (f)(7)(ii)(B) of this section.

* * * * *

(9) * * *

(i) * * *

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as an objective in this paragraph (d).

(ii) * * *

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as a measure in this paragraph (d).

* * * * *

(12) * * *

(i) * * *

(B) Beginning 2014, provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) * * *

(B) Beginning 2014, subject to paragraph (c) of this section, more than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

* * * * *

(13) * * *

(i) * * *

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2013, this measure is no longer required as part of the core set.

(g) * * *. Beginning in 2014, eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (g)(9), or (g)(10) of this section:

* * * * *

(8)(i) * * *

(B) Beginning in 2013, capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

(9)(i) * * *

(B) Beginning in 2013, capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(10)(i) * * *

(B) Beginning in 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(h) *Stage 2 criteria for EPs*—(1) *General rule regarding Stage 2 criteria for meaningful use for EPs.* Except as specified in paragraph (h)(2) of this section, EPs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (j) of this section and 3 objectives of the EP's choice from paragraph (k) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for nonapplicable objectives.* (i) An EP may exclude a particular objective contained in paragraphs (j) or (k) of this section, if the EP meets all of the following requirements:

(A) Must ensure that the objective in paragraph (j) or (k) of this section includes an option for the EP to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation.

(C) Attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (j) of this section. For example, an EP that has an exclusion from one of the objectives in paragraph (j) of this section must meet 16 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (k) of this section unless 4 or more exclusions apply. For example, an EP that has an exclusion for 1 of the objectives in paragraph (k) of this section must meet 3 of the 4 nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an EP has an exclusion for 4 of the objectives in paragraph (k) of this section, then he or she must meet the remaining the nonexcluded objective from such paragraph to meet the definition of a meaningful EHR user.

(i) *Stage 2 criteria for eligible hospitals and CAHs.* (1) *General rule regarding Stage 2 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraph (i)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (l) of this section and two objectives of the eligible hospital's or CAH's choice from paragraph (m) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusions for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (l) or (m) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (l) of this

section. For example, an eligible hospital that has an exclusion from 1 of the objectives in paragraph (l) of this section must meet 15 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (m) of this section unless 3 or more exclusions apply. For example, an eligible hospital that has an exclusion for 1 of the objectives in paragraph (m) of this section must meet 2 of the 3 non-excluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an eligible hospital has an exclusion for 3 of the objectives in paragraph (m) of this section, then the hospital must meet the remaining nonexcluded objective from such paragraph to meet the definition of a meaningful EHR user.

(j) *Stage 2 core criteria for EPs.* An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (h)(2) of this section specified in this paragraph (j).

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local, and professional guidelines to create the first record of the order.

(ii) *Measure.* More than 60 percent of medication, laboratory, and radiology orders created by the EP during the EHR reporting period are recorded using CPOE.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who writes fewer than 100 medication, laboratory, and radiology orders during the EHR reporting period.

(2)(i) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure.* More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who writes fewer than 100 prescriptions during the EHR reporting period or does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 miles of the EP's practice location at the start of his or her EHR reporting period.

(3)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.

(4)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0–20 years, including BMI.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who—

(A) Sees no patients 3 years or older is excluded from recording blood pressure;

(B) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(C) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(D) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(5)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* More than 80 percent of all unique patients 13 years old or older seen by the EP during the EHR reporting period have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who sees no patients 13 years old or older.

(6)(i) *Objective.* Use clinical decision support to improve performance on high priority health conditions.

(ii) *Measures.* (A) Implement five clinical decision support interventions related to five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period; and

(B) The EP has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(7)(i) *Objective.* Incorporate clinical lab-test results into Certified EHR Technology as structured data.

(ii) *Measure.* More than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who orders no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period.

(8)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Generate at least one report listing patients of the EP with a specific condition.

(9)(i) *Objective.* Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

(ii) *Measure.* More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has had no office visits in the 24 months before the beginning of the EHR reporting period.

(10)(i) *Objective.* Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

(ii) *Measures.* (A) More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information; and

(B) More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure is excluded from both paragraphs (i)(10)(ii)(A) and (B) of this section Any EP that conducts the majority (50 percent or more) of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband

availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (i)(10)(ii)(B) of this section.

(11)(i) *Objective.* Provide clinical summaries for patients for each office visit.

(ii) *Measure.* Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(12)(i) *Objective.* Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

(ii) *Measure.* Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(13)(i) *Objective.* The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* The EP performs medication reconciliation for more than 65 percent of transitions of care in which the patient is transitioned into the care of the EP.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who was not the recipient of any transitions of care during the EHR reporting period.

(14)(i) *Objective.* The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measures.* (A) The EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals; and

(B) The EP that transitions or refers their patient to another setting of care or provider of care electronically transmits using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender a summary of care record for more than 10 percent of transitions of care and referrals.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period is excluded from both measures.

(15)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP that meets one or more of the following criteria:

(A) The EP does not administer any of the immunizations to any of the populations for which data is collected by the jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(B) The EP operates in a jurisdiction for which no immunization registry or immunization information system is capable of receiving electronic immunization data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The EP operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the version of the standard that the EP's Certified EHR Technology can send at the start of their EHR reporting period.

(16)(i) *Objective.* Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.

(17)(i) *Objective.* Use secure electronic messaging to communicate with patients on relevant health information.

(ii) *Measure.* A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen by the EP during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(k) *Stage 2 menu set criteria for EPs.* An EP must meet 3 of the following objectives and associated measures, unless the EP meets 4 or more exclusions specified in this paragraph (k), in which case the EP must meet all remaining objectives and associated measures.

(1)(i) *Objective.* Imaging results and information are accessible through Certified EHR Technology.

(ii) *Measure.* More than 40 percent of all scans and tests whose result is one or more images ordered by the EP during the EHR reporting period are accessible through Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who does not perform diagnostic interpretation of scans or tests whose result is an image during the EHR reporting period.

(2)(i) *Objective.* Record patient family health history as structured data.

(ii) *Measure.* More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(3)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP that meets one or more of the following criteria:

(A) The EP is not in a category of providers who collect ambulatory syndromic surveillance information on their patients during the EHR reporting period.

(B) The EP operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The EP operates in a jurisdiction for which no public health agency is capable of accepting the version of the standard that the EP's Certified EHR Technology can send at the start of their EHR reporting period.

(4)(i) *Objective.* Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who—

(A) Does not diagnose or directly treat cancer; or

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(5)(i) *Objective.* Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who—

(A) Does not diagnose or directly treat any disease associated with a specialized registry; or

(B) Operates in a jurisdiction for which no registry is capable of receiving electronic specific case information in the specific standards required under Stage 2 at the beginning of their EHR reporting period.

(l) *Stage 2 core criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the following objectives and associated measures except those objectives and associated measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (i)(2) of this section.

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local, and professional guidelines to create the first record of the order.

(ii) *Measure.* More than 60 percent of medication, laboratory, and radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.

(2)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data.

(3)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0–20 years, including BMI.

(ii) *Measure:* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(4)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* More than 80 percent of all unique patients 13 years old or older admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that admits no patients 13 years old or older to their inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(5)(i) *Objective.* Use clinical decision support to improve performance on high priority health conditions.

(ii) *Measures.* (A) Implement five clinical decision support interventions related to five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period; and

(B) The eligible hospital or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the duration of the EHR reporting period.

(6)(i) *Objective.* Incorporate clinical lab-test results into Certified EHR Technology as structured data.

(ii) *Measure.* More than 55 percent of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data.

(7)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(ii) *Measure.* Generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(8)(i) *Objective.* Provide patients the ability to view online, download and transmit information about a hospital admission.

(ii) *Measures.* (A) More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge; and

(B) More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period is excluded from paragraph (l)(8)(ii)(B) of this section.

(9)(i) *Objective.* Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

(ii) *Measure.* More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.

(10)(i) *Objective.* The eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* The eligible hospital or CAH performs medication reconciliation for more than 65 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(11)(i) *Objective.* The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measures.* (A) The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals; and

(B) The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender a summary of care record for more than 10 percent of transitions of care and referrals.

(12)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) The eligible hospital or CAH does not administer any of the immunizations to any of the populations for which data is collected by the jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(B) The eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of receiving electronic immunization data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The eligible hospital or CAH does not have an immunization registry or immunization information system capable of accepting the version of the standard that the eligible hospital's or CAH's Certified EHR Technology can send at the start of their EHR reporting period.

(13)(i) *Objective.* Capability to submit electronic reportable laboratory results to public health agencies, where except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(14)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) The eligible hospital or CAH does not have an emergency or urgent care department.

(B) The eligible hospital or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The eligible hospital or CAH operates in a jurisdiction for which no public health agency is capable of accepting the version of standard that the eligible hospital's or CAH's Certified EHR Technology can send at the start of their EHR reporting period.

(15)(i) *Objective.* Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(16)(i) *Objective.* Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

(ii) *Measure.* eMAR is implemented and in use for the entire EHR reporting period in at least one ward/unit of the hospital.

(m) *Stage 2 menu set criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the measure criteria for two of the following objectives and associated measures.

(1)(i) *Objective.* Record whether a patient 65 years old or older has an advance directive.

(ii) *Measure.* More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR.

(2)(i) *Objective.* Imaging results and information are accessible through Certified EHR Technology.

(ii) *Measure.* More than 40 percent of all scans and tests whose result is an image ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through Certified EHR Technology.

(3)(i) *Objective.* Record patient family health history as structured data.

(ii) *Measure.* More than 20 percent of all unique patients admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

(4)(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *Measure.* More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared against at least one drug formulary and transmitted electronically using Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 25 miles.

8. Section 495.8 is amended as follows:

A. Revising paragraph (a)(2)(i)(B) and (a)(2)(ii).

B. Revising paragraphs (b)(2)(i)(B) and (b)(2)(ii).

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(B) Satisfied the required objectives and associated measures under § 495.6 for the EP's stage of meaningful use.

* * * * *

(ii) *Reporting clinical quality information.* Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

(b) * * *

(2) * * *

(i) * * *

(B) Satisfied the required objectives and associated measures under § 495.6 for the eligible hospital or CAH's stage of meaningful use.

* * * * *

(ii) *Reporting clinical quality information.* Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

9. Section 495.100 is amended by revising the definitions of ''Qualifying CAH,'' ''Qualifying eligible professional (qualifying EP),'' and ''Qualifying hospital'' to read as follows:

§ 495.100 Definitions.

* * * * *

Qualifying CAH means a CAH that is a meaningful EHR user for the EHR reporting period applicable to a payment year or payment adjustment year in which a cost reporting period begins.

Qualifying eligible professional (qualifying EP) means an EP who is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year and who is not a hospital-based EP, as determined for that payment or payment adjustment year.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year.

10. Section 495.102 is amended as follows:

A. Revising paragraphs (d)(1), (d)(2)(iii), and (d)(3).

B. Adding paragraphs (d)(2)(iv), (d)(4), and (d)(5).

The revisions and additions read as follows:

§ 495.102 Incentive payments to EPs.

* * * * *

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.* (1)(i) Subject to paragraphs (d)(3) and (d)(4) of this section, beginning in 2015, for covered professional services furnished by an EP who is not hospital-based, and who is not a qualifying EP by virtue of not being a meaningful EHR user (for the EHR reporting period applicable to the payment adjustment year), the payment amount for such services is equal the product of the applicable percent specified in paragraph (d)(2) of this section and the Medicare physician fee schedule amount for such services.

* * * * *

(2) * * *

(iii) For 2017, 97 percent.

(iv) For 2018 and subsequent years, 97 percent, except as provided in paragraph (d)(3) of this section.

(3) *Decrease in applicable percent in certain circumstances.* If, beginning with CY 2018 and for each subsequent year, the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent must be decreased by 1 percentage point for EPs from the applicable percent in the preceding year, but in no case will the applicable percent be less than 95 percent.

(4) *Exceptions.* The Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment under paragraph (d)(1) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the EP. To be considered for an exception, an EP must submit, in the manner specified by CMS, an application demonstrating that it meets one or more of the criteria in this paragraph (d)(4). The Secretary's determination to grant an EP an exemption may be renewed on an annual basis, provided that in no case may an EP be granted an exemption for more than 5 years.

(i) During the calendar year that is 2 years before the payment adjustment year, the EP was located in an area without sufficient Internet access to comply with the meaningful EHR use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year.

(ii) The EP has been practicing for less than 2 years.

(iii) During either of the 2 calendar years before the payment adjustment year, the EP faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year.

(5) *Payment adjustments not applicable to hospital-based EPs.* No payment adjustment under paragraphs (d)(1) through (3) of this section may be made in the case of a hospital-based eligible professional, as defined in § 495.4.

§ 495.106 [Amended]

11. In § 495.106, paragraph (e) is amended by removing the phrase ''for a payment year'' and adding the phrase ''for a payment adjustment year'' in its place.

12. Section 495.200 is amended by—

A. Adding definitions for ''Adverse eligibility determination,'' ''Adverse payment determination,'' ''MA payment adjustment year,'' and ''Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals'' in alphabetical order.

B. Revising paragraph (5) of the definition of ''Qualifying MA EP''.

The additions and revision read as follows:

§ 495.200 Definitions.

Adverse eligibility determination means a determination or omission by CMS that was the result of a malfunction of a CMS system that prohibits a qualifying MA organization, qualifying MA EP, or qualifying MA-affiliated eligible hospital from participating in the Medicare Advantage EHR Incentive Program.

Adverse payment determination means a determination by CMS that negatively affects an EHR payment determination under this subpart.

* * * * *

MA payment adjustment year means—(1) For qualifying MA organizations that receive an MA EHR incentive payment for at least 1 payment year, calendar years beginning with CY 2015.

(2) For MA-affiliated eligible hospitals, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the federal fiscal year ending in the payment adjustment year.

(3) For MA EPs, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the calendar year

concurrent with the payment adjustment year.

* * * * *

Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals are defined for purposes of this subpart in § 495.202(a)(4).

* * * * *

Qualifying MA EP * * *

* * * * *

(5) Is not a ''hospital-based EP'' (as defined in § 495.4 of this part) and in determining whether 90 percent or more of his or her covered professional services were furnished in a hospital setting, only covered professional services furnished to MA plan enrollees of the qualifying MA organization, in lieu of FFS patients, will be considered.

* * * * *

13. Section 495.202 is amended as follows:

A. Revising paragraph (b)(1).

B. In paragraph (b)(2) introductory text, removing the cross-reference ''(b)(3)'' and adding the cross-reference ''(b)(4)'' in its place.

C. In paragraph (b)(2)(iii), removing the term ''NPI.'' and adding the phrase ''NPI or CCN.'' in its place.

D. Redesignating paragraphs (b)(3) and (b)(4) as paragraphs (b)(4) and (b)(5).

E. Adding a new paragraph (b)(3).

F. Revising newly redesignated paragraph (b)(4).

G. Revising newly redesignated paragraphs (b)(5)(i) and (ii).

The addition and revisions read as follows:

§ 495.202 Identification of qualifying MA organizations, MA–EPs and MA-affiliated eligible hospitals.

* * * * *

(b) * * *

(1) A qualifying MA organization, as part of its initial bid starting with plan year 2012, must make a preliminary identification of MA EPs and MA-affiliated eligible hospitals that the MA organization believes will be qualifying MA EPs and MA-affiliated eligible hospitals for which the organization is seeking incentive payments for the current plan year.

* * * * *

(3) When reporting under either paragraph (b)(1) or (b)(4) of this section for purposes of receiving an incentive payment, a qualifying MA organization must also indicate whether more than 50 percent of the covered Medicare professional services being furnished by a qualifying MA EP to MA plan enrollees of the MA organization are being furnished in a designated geographic HPSA (as defined in § 495.100 of this part).

(4) Final identification of qualifying and potentially qualifying, as applicable, MA EPs and MA-affiliated eligible hospitals must be made within 2 months of the close of the payment year or the EHR reporting period that applies to the payment adjustment year as defined in § 495.200.

(5) * * *

(i) Identify all MA EPs and MA-affiliated eligible hospitals of the MA organization that the MA organization believes will be either qualifying or potentially qualifying;

(ii) Include information specified in paragraph (b)(2)(i) through (iii) of this section for each professional or hospital; and

* * * * *

14. Section 495.204 is amended as follows:

A. Revising the section heading.

B. Revising paragraphs (b)(2) and (b)(4).

C. Redesignating paragraph (e) as paragraph (f).

D. Adding new paragraphs (e), (f)(5), and (g).

The revisions and additions read as follows:

§ 495.204 Incentive payments to qualifying MA organizations for qualifying MA–EPs and qualifying MA-affiliated eligible hospitals.

* * * * *

(b) * * *

(2) The qualifying MA organization must report to CMS within 2 months of the close of the calendar year, the aggregate annual amount of revenue attributable to providing services that would otherwise be covered as professional services under Part B received by each qualifying MA EP for enrollees in MA plans of the MA organization in the payment year.

* * * * *

(4) CMS requires the qualifying MA organization to develop a methodological proposal for estimating the portion of each qualifying MA EP's salary or revenue attributable to providing services that would otherwise be covered as professional services under Part B to MA plan enrollees of the MA organization in the payment year. The methodological proposal—

(i) Must be approved by CMS; and

(ii) May include an additional amount related to overhead, where appropriate, estimated to account for the MA-enrollee related Part B practice costs of the qualifying MA EP.

* * * * *

(e) *Potential increase in incentive payment for furnishing services in a geographic HPSA.* In the case of a qualifying MA EP who furnishes more than 50 percent of his or her covered professional services to MA plan enrollees of the qualifying MA organization during a payment year in a geographic HPSA, the maximum amounts referred to in paragraph (b)(3) of this section are increased by 10 percent.

(f) * * *

(5) If an MA EP, or entity that employs an MA EP, or in which an MA EP has a partnership interest, MA-affiliated eligible hospital, or other party contracting with the MA organization, fails to comply with an audit request to produce applicable documents or data, CMS recoups all or a portion of the incentive payment, based on the lack of applicable documents or data.

(g) *Coordination of payment with FFS or Medicaid EHR incentive programs.* (1) If, after payment is made to an MA organization for an MA EP, it is determined that the MA EP is eligible for the full incentive payment under the Medicare FFS EHR Incentive Program or has received a payment under the Medicaid EHR Incentive Program, CMS recoups amounts applicable to the given MA EP from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

(2) If, after payment is made to an MA organization for an MA-affiliated eligible hospital, it is determined that the hospital is ineligible for the incentive payment under the MA EHR Incentive Program, or has received a payment under the Medicare FFS EHR Incentive Program, or if it is determined that all or part of the payment should not have been made on behalf of the MA-affiliated eligible hospital, CMS recoups amounts applicable to the given MA-affiliated eligible hospital from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

15. Section 495.208 is amended as follows:

A. Redesignating paragraphs (a) through (c) as paragraphs (d) through (f).

B. Adding new paragraphs (a) through (c).

The additions read as follows:

§ 495.208 Avoiding duplicate payment.

(a) CMS requires a qualifying MA organization that registers MA EPs for the purpose of participating in the MA EHR Incentive Program to notify each of the MA EPs for which it is claiming an incentive payment that the MA organization intends to claim, or has claimed, the MA EP for the current plan year under the MA EHR Incentive Program.

(b) The notice must make clear that the MA EP may still directly receive an EHR incentive payment if the MA EP is entitled to a full incentive payment under the FFS portion of the EHR Incentive Program, or if the MA EP registered to participate under the Medicaid portion of the EHR Incentive Program and is entitled to payment under that program—in both of which cases no payment would be made for the EP under the MA EHR incentive program.

(c) An attestation by the qualifying MA organization that the qualifying MA organization provided notice to its MA EPs in accordance with this section must be required at the time that meaningful use attestations are due with respect to MA EPs for the payment year.

* * * * *

16. Section 495.210 is amended by revising paragraphs (b) and (c) to read as follows:

§ 495.210 Meaningful EHR user attestation.

* * * * *

(b) Qualifying MA organizations are required to attest within 2 months after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user.

(c) Qualifying MA organizations are required to attest within 2 months after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user.

17. A new § 495.211 is added to subpart C to read as follows:

§ 495.211 Payment adjustments effective for 2015 and subsequent MA payment years with respect to MA EPs and MA-affiliated eligible hospitals.

(a) *In general.* Beginning for MA payment adjustment year 2015, payment adjustments set forth in this section are made to prospective payments (issued under section 1853(a)(1)(A) of the Act) of qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program, if all or a portion of the MA–EPs and MA-affiliated eligible hospitals that would meet the definition of qualifying MA–EPs or qualifying MA-affiliated eligible hospitals (but for their demonstration of meaningful use) are not meaningful EHR users.

(b) *Adjustment based on payment adjustment year.* The payment adjustment is calculated based on the payment adjustment year.

(c) *Separate application of adjustments for MA EPs and MA-affiliated eligible hospitals.* The payment adjustments identified in paragraphs (d) and (e) of this section are applied separately.

(d) *Payment adjustments effective for 2015 and subsequent years with respect to MA EPs.* (1) For payment adjustment year 2015, and subsequent payment adjustment years, if a qualifying MA EP is not a meaningful EHR user during the payment adjustment year, CMS—

(i) Determines a payment adjustment based on data from the payment adjustment year; and

(ii) Collects the payment adjustment owed by adjusting a subsequent year's prospective payment or payments (issued under section 1853(a)(1)(A) of the Act), or by otherwise collecting the payment adjustment, if, in the year of collection, the MA organization does not have an MA contract with CMS.

(2) Beginning for payment adjustment year 2015, a qualifying MA organization that previously received incentive payments must, for each payment adjustment year, report to CMS the following:

[The total number of potentially qualifying MA EPs]/[(the total number of potentially qualifying MA EPs) + (the total number of qualifying MA EPs)].

(3) The monthly prospective payment amount paid under section 1853(a)(1)(A) of the Act for the payment adjustment year is adjusted by the product of—

(i) The percent calculated in accordance with paragraph (d)(2) of this section;

(ii) The Medicare Physician Expenditure Proportion percent, which is CMS's estimate of proportion of expenditures under Parts A and B that are not attributable to Part C that are attributable to expenditures for physicians' services, adjusted for the proportion of expenditures that are provided by EPs that are neither qualifying nor potentially qualifying MA EPs with respect to a qualifying MA organization; and

(iii) The applicable percent identified in paragraph (d)(4) of this section.

(4) *Applicable percent.* The applicable percent is as follows:

(i) For 2015, 1 percent;

(ii) For 2016, 2 percent;

(iii) For 2017, 3 percent.

(iv) For 2018, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, 4 percent.

(v) For 2019 and each subsequent year, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, the percent from the prior year plus 1 percent. In no case will the applicable percent be higher than 5 percent.

(vi) Beginning with payment adjustment year 2018, if the percentage in paragraph (d)(2) of this section is more than 25 percent, the applicable percent is increased in accordance with paragraphs (d)(4)(iv) and (v) of this section.

(e) *Payment adjustments effective for 2015 and subsequent years with respect to MA-affiliated eligible hospitals.* (1)(i) The payment adjustment set forth in this paragraph (e) applies if a qualifying MA organization that previously received an incentive payment (or a potentially qualifying MA-affiliated eligible hospital on behalf of its qualifying MA organization) attests that a qualifying MA-affiliated eligible hospital is not a meaningful EHR user for a payment adjustment year.

(ii) The payment adjustment is calculated by multiplying the qualifying MA organization's monthly prospective payment for the payment adjustment year under section 1853(a)(1)(A) of the Act by the percent set forth in paragraph (e)(2) of this section.

(2) The percent set forth in this paragraph (e) is the product of—

(i) The percentage point reduction to the applicable percentage increase in the market basket index for the relevant Federal fiscal year as a result of § 412.64(d)(3) of this chapter;

(ii) The Medicare Hospital Expenditure Proportion percent specified in paragraph (e)(3) of this section; and

(iii) The percent of qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful EHR users. Qualifying MA organizations are required to report to CMS:

[The number of potentially qualifying MA-affiliated eligible hospitals]/[(the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)].

(3) The Medicare Hospital Expenditure Proportion for a year is the Secretary's estimate of expenditures under Parts A and B that are not attributable to Part C, that are attributable to expenditures for inpatient hospital services, adjusted for the proportion of expenditures that are provided by hospitals that are neither qualifying nor potentially qualifying MA-affiliated eligible hospitals with respect to a qualifying MA organization.

18. A new § 495.213 is added to subpart C to read as follows:

§ 495.213 Reconsideration process for a qualifying MA organization.

(a) *In general.* A qualifying MA organization may seek reconsideration of an adverse eligibility or payment determination in accordance with the requirements of this section.

(b) *Rejection of requests barred from administrative and judicial review.* Reconsideration requests prohibited under § 495.212 will be rejected.

(c) *Rejection of requests including new payment information.* Reconsideration requests that seek to include new payment-related information will be rejected.

(d) *Channeling of hospital and meaningful use reconsideration requests.* (1) All reconsideration requests involving MA-affiliated eligible hospitals must meet the requirements of and be channeled through the reconsideration process in subpart E of this part and will be rejected for reconsideration under this section.

(2) All reconsideration requests involving the meaningful use of Certified EHR Technology must follow the requirements of and be channeled through the reconsideration process in subpart E of this part and will be rejected for reconsideration under this section.

(e) *Informal reconsideration.* (1)(i) A qualifying MA organization must request an informal reconsideration in writing within 60 calendar days of an adverse eligibility or payment determination.

(ii) If the 60th calendar day occurs on a Saturday, Sunday or Federal holiday, the request for an informal reconsideration is due the calendar day following the Sunday or Federal holiday.

(2) The request for an informal reconsideration—(i) Must specify the finding(s) or issue(s) with which the qualifying MA organization disagrees and the reason(s) for the disagreement; and

(ii) May include additional documentary evidence that the qualifying MA organization wishes CMS to consider.

(3) An informal reconsideration decision is final and binding, absent reopening due to audit or other evidence of material misrepresentation, unless a request for a final reconsideration is requested in accordance with paragraph (f) of this section.

(f) *Final reconsideration.* (1)(i) A qualifying MA organization seeking a final reconsideration must request the final reconsideration in writing within 30 calendar days of the date on the notice issued as a result of the informal reconsideration.

(ii) If the 30th calendar day occurs on a Saturday, Sunday or Federal holiday, the request for a final reconsideration is due the calendar day following the Sunday or Federal holiday.

(2) The request for a final reconsideration must—

(i) Specify the finding(s) or issue(s) with which the qualifying MA organization disagrees and the reason(s) for the disagreement;

(ii) Include a copy of the documents and evidence submitted for the informal reconsideration and a copy of the decision issued in accordance with the informal reconsideration.

(iii) Not include new evidence or documents not presented at the informal reconsideration level.

(3) A final reconsideration is final and binding, absent reopening due to audit or other evidence of material misrepresentation.

19. Section 495.302 is amended as follows:

A. In the definition of ''Children's hospital,'' by revising paragraph (1), redesignating paragraph (2) as paragraph (3), and adding a new paragraph (2).

B. In the definition of ''Practices predominantly,'' by removing the phrase ''in the most recent calendar year occurs'' and adding the phrase ''(within the most recent calendar year or within the 12-month period preceding attestation)''.

The revision and addition reads as follows:

§ 495.302 Definitions.

* * * * *

Children's hospital * * *

(1) Has a CMS certification number (CCN), (previously known as the Medicare provider number), that has the last 4 digits in the series 3300–3399; or

(2) Does not have a CCN but has been provided an alternative number by CMS for purposes of enrollment in the Medicaid EHR Incentive Program as a children's hospital; and

* * * * *

20. Section 495.304 is amended as follows:

A. In paragraphs (c)(1) and (c)(2), by removing the phrase ''individuals receiving Medicaid'' and adding the phrase ''individuals enrolled in a Medicaid program'' in its place.

B. Adding paragraph (f).

The addition reads as follows:

§ 495.304 Medicaid provider scope and eligibility.

* * * * *

(f) *Further patient volume requirements for the Medicaid EP.* At least one clinical location used in the calculation of patient volume must have Certified EHR Technology—

(1) During the payment year for which the EP attests to having adopted, implemented or upgraded Certified EHR Technology (for the first payment year); or

(2) During the payment year for which the EP attests it is a meaningful EHR user.

21. Section 495.306 is amended as follows;

A. Revising paragraphs (b), (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), (d)(2)(ii)(A), and (e)(1) introductory text.

B. In paragraph (e)(1)(i), by removing ''; or'' and adding ''.'' in its place.

C. Adding paragraph (e)(1)(iii).

D. Revising paragraph (e)(2)(i) introductory text.

E. In paragraph (e)(2)(i)(A), by removing ''; or'' and adding ''.'' in its place.

F. Adding paragraph (e)(2)(i)(C).

G. Revising paragraph (e)(2)(ii) introductory text.

H. In paragraph (e)(2)(ii)(A), by removing ''; or'' and adding ''.'' in its place.

I. Adding paragraph (e)(2)(ii)(C).

J. Revising paragraph (e)(3) introductory text.

K. In paragraphs (e)(3)(i) and (ii), by removing ''; '' and adding ''.'' in its place.

L. In paragraph (e)(3)(iii), by removing ''; or'' and adding ''.'' in its place.

M. Redesignating paragraphs (e)(3)(iii) and (e)(3)(iv) as paragraphs (e)(3)(iv) and (e)(3)(v).

N. Adding a new paragraph (e)(3)(iii).

The revisions and additions read as follows:

§ 495.306 Establishing patient volume.

* * * * *

(b) *State option(s) through SMHP.* (1) A State must submit through the SMHP the option or options it has selected for measuring patient volume.

(2)(i) A State must select the method described in either paragraph (c) or paragraph (d) of section (or both methods).

(ii) Under paragraphs (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i), and (d)(2)(i) of this section, States may choose whether to allow eligible providers to calculate total Medicaid or total needy individual patient encounters in any representative continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation or based upon a representative, continuous 90-day period in the calendar year preceding the payment year for which the EP or eligible hospital is attesting.

(3) In addition, or as an alternative to the method selected in paragraph (b)(2) of this section, a State may select the method described in paragraph (g) of this section.

(c) * * *

(1) * * *

(i) The total Medicaid patient encounters in any representative,

continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

* * * * *

(2) * * *

(i) The total Medicaid encounters in any representative, continuous 90-day period in the fiscal year preceding the hospitals' payment year or in the 12 months before the hospital's attestation; by

* * * * *

(3) * * *

(i) The total needy individual patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

* * * * *

(d) * * *

(1) * * *

(i)(A) The total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Medicaid encounter took place with the individual in the 24 months before the beginning of the 90-day period; plus

* * * * *

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period; plus

* * * * *

(2) * * *

(i)(A) The total Needy Individual patients assigned to the EP's panel in any representative, continuous 90-day period in either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Needy Individual encounter took place with the individual in the 24 months before the beginning of the same 90-day period; plus

* * * * *

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period, plus

* * * * *

(e) * * *

(1) A Medicaid encounter means services rendered to an individual per inpatient discharge if any of the following occur:

* * * * *

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the service was provided.

(2) * * *

(i) A Medicaid encounter means services rendered to an individual per inpatient discharge when any of the following occur:

* * * * *

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the service was provided.

(ii) A Medicaid encounter means services rendered in an emergency department on any 1 day if any of the following occur:

* * * * *

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the service was provided.

(3) For purposes of calculating needy individual patient volume, a needy patient encounter means services rendered to an individual on any 1 day if any of the following occur:

* * * * *

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the service was provided.

* * * * *

22. Section 495.310 is amended as follows:

A. Removing and reserving paragraphs (a)(1)(ii) and (a)(2)(ii).

B. Adding paragraph (f)(8).

C. Revising the second sentence of paragraph (g)(1)(i)(B) introductory text.

D. In paragraphs (g)(1)(i)(B)(*1*) through (g)(1)(i)(B)(*3*), by removing the term ''discharge'' wherever it appears and adding the term ''acute-care inpatient discharge'' in its place.

E. In paragraph (g)(1)(i)(C), by removing the term ''discharges'' and adding the term ''acute-care inpatient discharges'' in its place.

F. In paragraphs (g)(2)(i)(A) and (B), (g)(2)(ii)(A), and (g)(2)(iii), by removing the phrase ''inpatient-bed-days'' wherever it appears and adding the phrase ''acute care inpatient-bed-days'' in its place.

The addition and revision read as follows:

§ 495.310 Medicaid provider incentive payments.

(a) * * *

(1) * * *

(ii) [Reserved].

(2) * * *

(ii) [Reserved].

* * * * *

(f) * * *

(8) The aggregate EHR hospital incentive amount calculated under paragraph (g) of this section is determined by the State from which the eligible hospital receives its first payment year incentive. If a hospital receives incentive payments from other States in subsequent years, total incentive payments received over all payment years of the program can be no greater than the aggregate EHR incentive amount calculated by the initial State.

(g) * * *

(1) * * *

(B) * * *. The discharge-related amount is the sum of the following, with acute-care inpatient discharges over the 12-month period and based upon the total acute-care inpatient discharges for the eligible hospital (regardless of any source of payment):

* * * * *

23. Section 495.312 is amended by revising paragraph (c) to read as follows:

§ 495.312 Process for payments.

* * * * *

(c) *State's role.* (1) Except as specified in paragraph (c)(2) of this section, the State determines the provider's eligibility for the EHR incentive payment under subparts A and D of this part and approves, processes, and makes timely payments using a process approved by CMS.

(2) At the State's option, CMS conducts the audits and handles any subsequent appeals, of whether eligible hospitals are meaningful EHR users on the States' behalf.

* * * * *

24. Section 495.332 is amended as follows:

A. Adding a new paragraph (b)(6).

B. Revising paragraph (c) introductory text.

C. Removing paragraph (d)(9).

D. Adding a new paragraph (g).

The revisions and additions read as follows:

§ 495.332 State Medicaid health information technology (HIT) plan requirements.

* * * * *

(b) * * *

(6) For ensuring that at least one clinical location used for the calculation of the EP's patient volume has Certified EHR Technology during the payment year for which the EP is attesting.

(c) Subject to paragraph (g) of this section, for monitoring and validation of information States must include the following:

* * * * *

(g) At the State's option, the State may include a signed agreement indicating that the State does all of the following:

(1) Designates CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations.

(2) Is bound by the audit and appeal findings described in paragraph (g)(1) of this section.

(3) Performs any necessary recoupments if audits (and any subsequent appeals) described in paragraph (g)(1) of this section determine that an eligible hospital was not a meaningful EHR user.

(4) Is liable for any FFP granted to the State to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users.

25. Section 495.342 is amended by revising the introductory text to read as follows:

§ 495.342 Annual HIT IAPD requirements.

Each State is required to submit the HIT IAPD Updates a minimum of 12 months from the date of the last CMS approved HIT IAPD and must contain the following:

* * * * *

26. Section 495.370 is amended by adding a new paragraph (d) to read as follows:

§ 495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

* * * * *

(d) This section does not apply in the case that CMS conducts the audits and handles any subsequent appeals under § 495.312(c)(2) of this part.

27. Add a new subpart E to read as follows:

Subpart E—Administrative Review of Certain Electronic Health Record Incentive Program Determinations

Sec.

Subpart E—Administrative Review of Certain Electronic Health Record Incentive Program Determinations

§ 495.400 Basis and purpose.

This subpart—

(a) Contains an administrative appeal process for Medicare EPs, eligible hospitals, and CAHs, and, in certain cases, Medicaid eligible hospitals and potentially qualifying MA EPs and MA-affiliated eligible hospitals; and

(b) Defines the types of appeals and issues that may be raised on appeal as well as the documents or data, or both, that must be submitted to support issues raised in the appeal filing.

§ 495.402 Definitions.

For purposes of this subpart, the following definitions apply:

Circumstance outside a provider's control means any event that reasonably prevented a provider from participating in the EHR Incentive Program and which the provider could not under any circumstances control.

Eligibility appeal means any of the following:

(1) An appeal filed by a provider that can demonstrate it met all program requirements for the EHR Incentive Program and should have received a payment but could not because of circumstances outside a provider's control. A provider must also demonstrate an action to participate in the EHR Incentive Program.

(2) An appeal of whether a hospital may be considered a potentially qualifying MA-affiliated eligible hospital, as defined under § 495.200, based on common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans, as well as whether less than one-third of Medicare bed-days for the year are covered under Part A rather than Part C.

Incentive payment appeal means an appeal challenging only the total estimated allowed charges for a qualifying EP's covered professional services under § 495.102(b) of this part. The appeal could not contest an individual claims payment or coverage decisions, but only the inclusion of final claims used to calculate the incentive payment amount or the inclusion of claims used to calculate the incentive payment amount. Incentive payment appeals may also include appeals challenging a subsequent Federal determination that the incentive payment calculation amount was incorrect (including determinations that the incentive payment was duplicative).

Meaningful use appeal means an appeal challenging a determination or finding that a provider was not a meaningful EHR user, or that it did not use Certified EHR Technology.

Permissible appeal means an eligibility appeal, a meaningful use appeal, or an incentive payment appeal.

Provider means one of the following entities that is permitted to file an appeal in accordance with the requirements specified in this subpart:

(1) An EP.

(2) An eligible hospital.

(3) A CAH.

(4) A qualifying MA organization on behalf of a potentially qualifying MA EP.

(5) A potentially qualifying MA-affiliated eligible hospital.

(6) A Medicaid eligible hospital.

§ 495.404 Provider scope and eligibility to file.

Subject to the limitations and requirements contained in this subpart, only permissible appeals are permitted to be filed, only the following providers may file appeals, and only for the types of appeals specified in this section:

(a) An EP as defined under § 495.100 is permitted to file an eligibility appeal, a meaningful use appeal, or an incentive payment appeal.

(b) An eligible hospital as defined under § 495.100 is permitted to file an eligibility appeal or a meaningful use appeal.

(c) A CAH as defined under § 495.4 is permitted to file an eligibility appeal or a meaningful use appeal.

(d) A qualifying MA organization as defined under § 495.200 is permitted to file a meaningful use appeal for a potentially qualifying MA EP as defined under § 495.200 who has been determined not to be a meaningful EHR user.

(e) A potentially qualifying MA-affiliated eligible hospital as defined under § 495.200 is permitted to file an eligibility appeal described in paragraph (ii) of the definition (that is, an appeal based on common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed days) are of (or for) Medicare individuals enrolled under MA plans and/or whether less than one-third of Medicare bed-days for the year are covered under Part A rather than Part C) and a meaningful use appeal if determined not to be a meaningful EHR user.

(f) A Medicaid-eligible hospital under subpart D of this part is permitted to file a meaningful use appeal, but only in the case that an adverse audit has been conducted by CMS.

§ 495.406 Filing appeals.

A provider must make all filings or requests, and submit all documentation, comments, and data through an online mechanism and in a manner specified by CMS.

§ 495.408 General filing rules.

(a) *All relevant issues raised in initial filing of appeal.* Except under extenuating circumstances described in paragraph (c)(1) of this section, a provider must raise all relevant issues at the time of the initial filing of an appeal.

(b) *Deadlines for filing appeals.* (1) *General rules.* (i) Except under extenuating circumstances described in paragraph (c)(2) of this section, an appeal filed by a provider after the specified deadline is dismissed and cannot be refiled.

(ii) If the filing deadline falls on a Saturday, Sunday, or a Federal holiday then the deadline for filing the appeal is extended to the next business day.

(iii) CMS may extend the filing deadline for providers in response to extenuating circumstances that occur within the EHR Incentive Program. CMS will provide information on our Web site at least 7 calendar days before the filing deadline providing the new filing deadline.

(2) *Deadline for an eligibility appeal.* An eligibility appeal must be filed no later than 30 days after the 2-month period following the payment year.

(3) *Deadline for a meaningful use appeal.* A meaningful use appeal must be filed no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive payment.

(4) *Deadline for an incentive payment appeal.* An incentive payment appeal must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any Federal determination that the incentive payment amount was incorrect (including determinations that the payment was duplicative).

(c) *Extenuating circumstances for filing*—(1) *Amendment to raise additional issues.* A provider—

(i) May file an amendment to raise additional issues, if the provider can demonstrate an extenuating circumstance existed that prevented all relevant issues from being included at the time of the initial filing of the appeal;

(ii) Must show, in its amendment request, that extenuating circumstances existed by submitting documentation of occurrences, events, or transactions that prevented the additional issues from being raised in the initial appeal filing; and

(iii) Must file its amendment claiming an extenuating circumstance within 15 days after the initial filing of the appeal.

(2) *Request an extension of the filing deadline.* (i) A provider—

(A) May file a request to extend the deadline under paragraph (b) of this section, if the provider can demonstrate an extenuating circumstance existed that prevented the appeal from being filed by the applicable deadline; and

(B) Must show, in its extension request, that extenuating circumstances existed by submitting documentation of occurrences, events, or transactions that prevented the appeal from being filed by the applicable deadline.

(ii) The length of an extension granted by CMS is based upon documentation filed and the reason(s) requested.

(iii) A request to extend the deadline must be filed before the deadline expires for the appeal the provider is filing.

(d) *Withdrawal of appeal filing.* A provider may withdraw an appeal at any time after the initial appeal filing and before an informal review decision is issued. The issues raised in the appeal filing may be re-filed by the provider before the deadline specified in paragraph (b) of this section.

§ 495.410 Other requirements.

(a) *General rule.* CMS reviews each issue raised in the appeal filing to determine if each issue is precluded from the appeals process. Appeal issues found to be precluded will be dismissed.

(b) *Judicial and administrative review.* Providers have the burden of demonstrating that each issue raised in the appeal filing is not precluded from administrative and judicial review under the Act and implementing regulations at 42 CFR 413.70(a)(7), 495.106(f), 495.110, and 495.212.

(c) *Inchoate issues.* (1) A provider has the burden of doing all of the following:

(i) Demonstrating that the provider met all the EHR Incentive Program requirements other than the issue raised and should have received an incentive payment for the payment year for which the appeal is filed.

(ii) Demonstrating that before the end of the payment year for which the appeal is filed, the provider allowed CMS an opportunity to resolve the issue that is raised in the appeal.

(iii) Demonstrating that CMS was not able to resolve the issue by the end of the 2 months following the payment year for which the appeal is filed.

(2) The provider must provide documentation of the resolution efforts described in paragraph (c)(1)(ii) of this section.

(d) *Hospital cost report issues.* Any issue involving an incentive payment based upon a hospital cost report must be filed with the Provider Reimbursement and Review Board. Issues raised in an appeal filing that involve a hospital cost report will be dismissed in accordance with these rules.

§ 495.412 Informal review process and decision.

(a) *General rule.* The informal review process is the first level review in the appeals process.

(b) *Supporting documentation*—(1) *Request for additional supporting documentation essential to validate an issue raised in the appeal.* During the informal review process, CMS may request supporting documentation from a provider for an issue that is raised in the appeal. Except in extenuating circumstances described in this paragraph (b), a provider has 7 calendar days to comply with the request for supporting documentation.

(2) *Failure to submit supporting documentation.* An issue raised in the appeal is dismissed if a provider fails to submit supporting documentation within 7 calendar days from the date of the request by CMS.

(3) *Request for extension before the supporting documentation deadline.* A request for an extension to submit supporting documentation may be filed if a provider can demonstrate an extenuating circumstance existed that prevented the supporting documentation from being filed by the provider within 7 calendar days.

(i) A provider must show extenuating circumstances existed by providing, with its request for extension, documentation of occurrences, events, or transactions that prevented a request from being complied within 7 calendar days. A request for an extension must be filed before the 7 calendar days to respond to the request has expired.

(ii) A request for an extension of the time period to submit supporting documentation must be filed within 7 calendar days from the date the request was made by CMS.

(iii) The length of an extension granted by CMS is based upon documentation submitted and the reasons requested.

(c) *Informal review standards.* All appeal requests are reviewed according to the guidelines associated with the specific appeal type.

(1) *Eligibility appeals.* A provider must do all of the following:

(i) Demonstrate that the provider can meet all of the requirements of the EHR except for the issue raised.

(ii) Except for eligibility appeals described in part (ii) of the definition (that is, appeals involving common corporate governance with a qualifying MA organization, for which at least two-

thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans and/or whether less than one-third of Medicare bed-days for the year are covered under Part A rather than Part C), demonstrate that the issue raised in the appeal filing was the result of a circumstance outside of a provider's control and prevented the provider from receiving an incentive payment.

(iii) Submit evidence that an action was taken to participate in the EHR Incentive Program.

(iv) For eligibility appeals described in part (ii) of the definition, demonstrate in accordance with subpart C of this part that either:

(A) The MA-affiliated hospital is under common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans; and/or

(B) The MA-affiliated eligible hospital has less than one-third of Medicare bed-days for the year covered under Part A rather than Part C.

(2) *Meaningful use appeals.* A provider must do all of the following:

(i) Demonstrate that the provider successfully meets the meaningful use objective and associated measure discussed in the demand letter or other finding for recoupment of the EHR incentive payment.

(ii) Demonstrate that the provider used Certified EHR Technology during the EHR reporting period for the payment year for which the appeal was filed.

(3) *Incentive payment appeals.* Providers appealing the amount of the incentive payment must do the following:

(i) Demonstrate that all relevant claims were submitted timely and appropriately and were either not used or misused in accordance with § 495.102(a)(2) of this part.

(ii) Demonstrate that the timely and appropriately submitted claims were not used in calculating the amount of the EHR incentive payment.

(d) *Informal review decision.* (1) CMS issues an informal review decision within 90 days of the initial appeal filing, unless an extension or amendment was granted to the provider or CMS.

(2) An informal review decision under this section represents CMS's final decision, unless a provider files a reconsideration request under § 495.414 of this subpart.

§ 495.414 Final reconsiderations.

(a) *Reconsideration request.* A provider dissatisfied with the CMS informal review decision under § 495.412 of this part may file a request for reconsideration of issues denied in that decision. The request for reconsideration may include comments and documentation to support the position that the issues raised in the appeal should not have been denied.

(b) *Deadline for reconsideration requests.* (1) Except as provided in paragraph (b)(2) of this section, reconsideration requests must be filed within 15 days from the date of the informal review decision.

(2) A provider may request a one-time extension of 15 additional days to file the reconsideration request, if the provider can demonstrate that the informal review decision was not received by the provider (or provider's representative) within 5 days from the date of the decision.

(c) *Final decision.* CMS renders a final decision within 10 days of the date the provider files the request for reconsideration.

(d) *Reconsideration request not filed.* If a provider does not file a request for reconsideration within the time period specified in paragraph (b) of this section, then the informal review decision is CMS's final decision.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 8, 2012.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 21, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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Part III

Department of Health and Human Services

45 CFR Part 170
Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB82

Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: Under section 3004 of the Public Health Service Act, the Secretary of Health and Human Services is proposing to revise the initial set of standards, implementation specifications, and certification criteria adopted in an interim final rule published on January 13, 2010, and a subsequent final rule that was published on July 28, 2010, as well as to adopt new standards, implementation specifications, and certification criteria. The proposed new and revised certification criteria would establish the technical capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal year and calendar year 2014. This notice of proposed rulemaking also proposes revisions to the permanent certification program for health information technology, which includes changing the program's name.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on May 7, 2012.

ADDRESSES: You may submit comments, identified by RIN 0991–AB82, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201. Please submit one original and two copies.
- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To enhance the accessibility and ease with which the public may comment on this proposed rule, a copy will be made available in Microsoft Word format. We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document will be made available for the public to use to provide comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on the certification criteria and associated standards and implementation specifications and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments or to use it as an addendum to narrative cover pages. Because of the technical nature of this proposed rule, we believe that use of the document may facilitate our review and understanding of the comments received. The Microsoft Word version of the proposed rule and the document that can be used for providing comments can be found at *http://www.regulations.gov* as part of this proposed rule's docket and on ONC's Web site (*http://healthit.hhs.gov*).

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Commonly Used Acronyms

CAH Critical Access Hospital
CDA Clinical Document Architecture
CDS Clinical Decision Support
CEHRT Certified EHR Technology
CHPL Certified HIT Products List
CMS Centers for Medicare & Medicaid Services
CQM Clinical Quality Measure
CY Calendar Year
EH Eligible Hospital
EHR Electronic Health Record
EP Eligible Professional
FY Fiscal Year
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HITPC HIT Policy Committee
HITSC HIT Standards Committee
HL7 Health Level Seven
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification

I. Executive Summary

A. Purpose of Regulatory Action

The HIT Standards Committee (HITSC) issued recommendations for standards, implementation specifications, and certification criteria to the National Coordinator for Health Information Technology (the National Coordinator) on September 28, 2011 and October 21, 2011. In fulfilling his duties under sections 3001(c)(1)(A) and (B) of the Public Health Service Act (PHSA), the National Coordinator reviewed the recommendations made by the HITSC, endorsed certain standards, implementation specifications, and certification criteria, and reported his determinations to the Secretary for consideration. This proposed rule serves as the Secretary's publication of her determinations regarding the standards, implementation specifications, and certification criteria endorsed by the National Coordinator, as required by section 3004(a)(3) of the PHSA.

The adoption by the Secretary, under sections 3004(a)(3) and 3004(b)(3) of the PHSA, of the standards, implementation specifications, and certification criteria proposed in this rule would establish the technical capabilities that electronic health record (EHR) technology must include to be certified. EHR technology certified to these standards, implementation specifications, and certification criteria makes it possible for eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) to adopt Certified EHR Technology (CEHRT) and subsequently attempt to demonstrate its meaningful use (MU) under the Medicare and Medicaid EHR Incentive Programs (the ''EHR Incentive Programs'') beginning with the EHR reporting periods in Federal fiscal year (FY) 2014 for EHs and CAHs and calendar year (CY) 2014 for EPs (hereafter referred to as ''FY/CY 2014'').

Consistent with Executive Order 13563, we have undertaken a retrospective review of our regulations. The proposed rule introduces multiple means for reducing regulatory burden and increasing regulatory flexibility for stakeholders, including proposed changes to current regulatory requirements and approaches.

B. Summary of Major Provisions

1. Overview of the 2014 Edition EHR Certification Criteria

We propose to adopt certification criteria that will support the proposed changes to the EHR Incentive Programs, including the new and revised objectives and measures for Stages 1 and 2 of MU proposed by CMS. The certification criteria we propose for adoption would also enhance care coordination, patient engagement, and the security, safety, and efficacy of EHR technology. For clarity, we refer to the certification criteria proposed for adoption as the 2014 Edition EHR certification criteria and the currently adopted certification criteria as the 2011 Edition EHR certification criteria. To permit efficient certification methods and reduce regulatory burden, we have identified those certification criteria that we propose to include in the 2014 Edition EHR certification criteria that include unchanged capabilities that were also included in the 2011 Edition EHR certification criteria. For EHR technology previously certified to the 2011 Edition EHR certification criteria, this would permit, where applicable, the use of prior test results for certification to the 2014 Edition EHR certification criteria (see the discussion of ''gap certification'' in section III.A.7 of this preamble).

2. Certified EHR Technology

Since the publication of the Standards and Certification Criteria final rule in July 2010, HHS has received significant

feedback from stakeholders suggesting that we change our CEHRT policy (and definition) to one that would provide EPs, EHs, and CAHs the flexibility to have only the EHR technology they need to demonstrate MU. Consistent with stakeholder feedback and recommendations received from the HITSC, this rule proposes to revise the definition of CEHRT. Of most significance, beginning with the EHR reporting periods in FY/CY 2014, we are proposing a revised definition of CEHRT that would provide more flexibility for EPs, EHs, and CAHs. In sum, in order to have EHR technology that meets the definition of CEHRT for FY and CY 2014 and subsequent years, EPs, EHs, and CAHs would be required to have a Base EHR (EHR technology that includes fundamental capabilities all providers would need to have) as well as the additional EHR technology necessary to meet the MU objectives and measures for the stage of MU that they seek to meet and to capture, calculate, and report clinical quality measures. We further discuss this proposal, including the concept of a ''Base EHR'' in section III.C (Redefining Certified EHR Technology and Related Terms).

3. ONC HIT Certification Program

This rule proposes revisions to the permanent certification program which aim to increase regulatory clarity and transparency, reduce regulatory burden, and add flexibility for the health information technology (HIT) community. One of these revisions includes changing the permanent certification program title to the ''ONC HIT Certification Program,'' which provides clearer attribution to the agency responsible for the program and an appropriate description of the program's scope, covering both current and potential future activities. The rule also proposes to revise the process for permitting the use of newer versions of ''minimum standard'' code sets. The proposed new approach seeks to reduce regulatory complexity and burden by providing the industry with the flexibility to quickly utilize newer versions of adopted ''minimum standard'' code sets. The rule proposes to modify the certification processes ONC–Authorized Certification Bodies (ONC–ACBs) would need to follow for certifying EHR Modules as a means of providing clear implementation direction and compliance with proposed new certification criteria, and also proposes to reduce regulatory burden by eliminating the certification requirement that every EHR Module be certified to the ''privacy and security'' certification criteria. Instead, the privacy and security capabilities are included in the Base EHR that must be a part of every EP's, EH's, and CAH's CEHRT. To increase clarity for the HIT market, we propose methods for clearly representing certified Complete EHRs and certified EHR Modules, including the representation of a ''Base EHR.'' Finally, we propose to require that test results used for the certification of EHR technology be available to the public in an effort to increase transparency around the certification process.

C. Costs and Benefits

We determined that this proposed rule is not an economically significant rule as its overall costs will be less than $100 million per year. We have, however, estimated the costs and benefits of the proposed rule. The estimated costs expected to be incurred by EHR technology developers to develop and prepare EHR technology (i.e., Complete EHRs and EHR Modules) to be tested and certified in accordance with the proposed certification criteria are represented in monetary terms in Table 1 below. We believe that there will be market pressures to have certified Complete EHRs and certified EHR Modules ready and available prior to when EPs, EHs, and CAHs must meet the proposed revised definition of CEHRT for FY/CY 2014. We assume this factor will cause a greater number of developers to prepare EHR technology for testing and certification towards the end of 2012 and throughout 2013, rather than in 2014. As a result, we believe, as represented in Table 1, that the costs attributable to this proposed rule will be distributed as follows: 40% for 2012, 50% for 2013, and 10% for 2014. The dollar amounts expressed in Table 1 are expressed in 2012 dollars.

There are multiple potential benefits from the adoption of the proposed certification criteria in this rule. Foremost, EHR technology certified to the proposed certification criteria would be capable of supporting EPs, EHs, and CAHs' attempts to demonstrate MU under the EHR Incentive Programs. The certification criteria also promote enhanced interoperability, functionality, utility, and security of EHR technology through the capabilities they include and the standards they require EHR technology to meet for certification. Proposals such as the revised definition of CEHRT, the availability of gap certification, and the proposed revisions to the permanent certification program, will, as noted, increase regulatory clarity, improve transparency, and add flexibility, while also reducing the regulatory burden on the HIT industry. Finally, we believe the proposals in this rule will support other initiatives, such as the Partnership for Patients.

TABLE 1—ESTIMATED COSTS OF THE PROPOSED RULE: DISTRIBUTED TOTAL PREPARATION COSTS FOR COMPLETE EHR AND EHR MODULE DEVELOPERS (3-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio percent	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2012	40	36.80	95.01	65.91
2013	50	46.01	118.76	82.38
2014	10	9.20	23.75	16.48
3–Year Totals	.....	92.01	237.52	167.53

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the PHSA and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange.

1. Standards, Implementation Specifications, and Certification Criteria

With the passage of the HITECH Act, two new Federal advisory committees were established, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC) (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator on different aspects of standards, implementation specifications, and certification criteria. The HITPC is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria, while the HITSC is responsible for recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA titled ''Subsequent Standards Activity'' provides that the ''Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent'' with the schedule published by the HITSC. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITSC and endorsed by the National Coordinator, as well as other appropriate and necessary HIT standards, implementation specifications, and certification criteria. Throughout this process, the Secretary intends to continue to seek the insights and recommendations of the HITSC.

2. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the ''National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle'' (i.e., certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also ''include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act.''

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HITSC, ''shall support the establishment of a conformance testing infrastructure, including the development of technical test beds.'' The HITECH Act also indicates that ''[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.''

B. Regulatory History

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria Interim Final and Final Rules

The Secretary issued an interim final rule with request for comments titled ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' (75 FR 2014, Jan. 13, 2010) (the ''S&CC January 2010 interim final rule''), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the S&CC January 2010 interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for MU Stage 1. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule, 75 FR 44590 (July 28, 2010) (the ''S&CC July 2010 final rule''). On October 13, 2010, an interim final rule with a request for comment was issued to remove certain implementation specifications related to public health surveillance that had been previously adopted in the S&CC July 2010 final rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the S&CC July 2010 final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of MU Stage 1 by EPs, EHs, and CAHs under the Medicare and Medicaid EHR Incentive Programs Stage 1 final rule (the ''EHR Incentive Programs Stage 1 final rule'') (see 75 FR 44314 for more information about MU and the Stage 1 requirements).

2. Medicare and Medicaid EHR Incentive Programs Stage 1 Proposed and Final Rules

On January 13, 2010, CMS published the EHR Incentive Programs Stage 1 proposed rule (75 FR 1844). The rule proposed a definition for Stage 1 MU of CEHRT and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. Subsequently, CMS published a final rule (75 FR 44314) for the EHR Incentive Programs on July 28, 2010, simultaneously with the publication of the S&CC July 2010 final rule. The EHR Incentive Programs Stage 1 final rule established the objectives, associated measures, and other requirements that EPs, EHs, and CAHs must satisfy to demonstrate MU during Stage 1.

3. HIT Certification Programs Proposed Rule and the Temporary and Permanent Certification Programs Final Rules

On March 10, 2010, ONC published a proposed rule (75 FR 11328) titled ''Proposed Establishment of Certification Programs for Health Information Technology'' (the ''Certification Programs proposed rule''). The rule proposed both a temporary and permanent certification program for the purposes of testing and certifying HIT. It also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT. A final rule establishing the temporary certification program was published on June 24, 2010 (75 FR 36158) (the ''Temporary Certification Program final rule'') and a final rule establishing the permanent certification program was published on January 7, 2011 (76 FR 1262) (''the

Permanent Certification Program final rule'').

III. Provisions of the Proposed Rule Affecting Standards, Implementation Specifications, and Certification Criteria

In the S&CC July 2010 final rule, the Secretary adopted certification criteria in title 45, part 170, §§ 170.302, 170.304, and 170.306 of the Code of Federal Regulations. To make a clear distinction between these previously adopted certification criteria and the ones discussed in this proposed rule, we will refer to the certification criteria adopted in the S&CC July 2010 final rule and included in §§ 170.302, 170.304, and 170.306 collectively as the ''2011 Edition EHR certification criteria'' and propose to revise § 170.102 to add this definition.

A. 2014 Edition EHR Certification Criteria

This rule proposes new, revised, and unchanged certification criteria that would establish the technical capabilities and specify the related standards and implementation specifications that CEHRT would need to include to, at a minimum, support the achievement of MU by EPs, EHs, and CAHs under the EHR Incentive Programs beginning with the EHR reporting periods in FY/CY 2014. We refer to these new, revised, and unchanged certification criteria as the ''2014 Edition EHR certification criteria'' and propose to add this term and its definition to § 170.102. Additionally, we propose to codify the 2014 Edition EHR certification criteria in section 170.314 to set them apart and make it easier for stakeholders to quickly determine which certification criteria would be required beginning with the EHR reporting periods that start in FY/CY 2014. This approach, coupled with our reference to the 2011 Edition EHR certification criteria, should eliminate any ambiguity and provide a clear distinction between the certification criteria that are part of the 2011 Edition EHR certification criteria and those we propose to include in the 2014 Edition EHR certification criteria. Further, we believe the inclusion of all 2014 Edition EHR certification criteria in one regulatory section will simplify the regulatory framework for stakeholders.

Many of the certification criteria that we propose in this rule are intended to support the MU objectives and measures proposed in the CMS Medicare and Medicaid EHR Incentive Programs Stage 2 proposed rule (Stage 2 proposed rule)[1] as well as the reporting of MU objectives and measures and clinical quality measures (CQMs) to CMS. To the extent CMS may change (e.g., add, revise, or remove) MU objectives, measures, or reporting requirements in a final rule, we may also find it necessary or appropriate to change proposed supporting certification criteria. Commenters recommending changes to the proposed MU objectives and measures, CQMs, or reporting requirements should consider whether changes to the certification criteria would also be needed and offer those suggested changes. Similarly, commenters should consider and specify whether any of their suggested revisions to the proposed certification criteria would impact the proposals in CMS's Stage 2 proposed rule.

We discuss the new, revised, and unchanged certification criteria that we propose to adopt as the 2014 Edition EHR certification criteria in sections A.4 through A.6 below. We specify where the proposed certification criteria would be included in § 170.314. We include a table at the beginning of the discussion of each certification criterion or criteria that specifies the MU objective that the proposed 2014 Edition EHR certification criterion or criteria and associated standards and implementation specifications support. The objective cited is either a proposed Stage 1 or Stage 2 objective that would be effective for the EHR reporting periods in FY/CY 2014. We provide this frame of reference because we propose that beginning in FY/CY 2014 EHR technology would need to be certified to the 2014 Edition EHR certification criteria to meet the definition of CEHRT and the table permits commenters to easily associate the certification criterion with the MU objective it supports. We provide the rationale for the proposed certification criteria, including citing the recommendations of the HITPC and HITSC, where appropriate. Last, in certain instances, we specifically request comment on the maturity and industry-acceptance of various standards and implementation specifications.

1. Applicability

Section 170.300 establishes the applicability of subpart C—Certification Criteria for Health Information Technology. Section 170.300(a) establishes the applicability of the adopted certification criteria to the testing and certification of Complete EHRs and EHR Modules. Section 170.300(b) specifies that when a certification criterion refers to two or more standards as alternatives, the use of at least one of the alternative standards will be considered compliant. Section 170.300(c) specifies that Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional. We propose to revise § 170.300 to reflect our proposed regulatory structure for the 2014 Edition EHR certification criteria. We propose to revise paragraph (c) to add that Complete EHRs and EHR Modules are also not required to be certified to specific capabilities within a certification criterion that are designated as optional. We also propose to add a paragraph (d) that would clarify which certification criteria or specific capabilities within a certification criterion included in § 170.314 have general applicability (i.e., apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting.

2. Scope of a Certification Criterion for Certification

In the certification programs final rules (75 FR 36176, 76 FR 1290–91) and the S&CC July 2010 final rule (75 FR 44622), we clarified that a single certification criterion would encompass all of the specific capabilities referenced below the first paragraph level. As an example in the Permanent Certification Program final rule, we stated that the certification criterion at 45 CFR 170.302, paragraph ''(f)'' (the first paragraph level) identifies that the certification criterion relates to recording and charting vital signs. The certification criterion includes three specific capabilities at (f)(1), (2), and (3) (the second paragraph level): The ability to record, modify, and retrieve patients' vital signs; the ability to calculate body mass index (BMI); and the ability to plot and display growth charts. We stated that we viewed the entire set of specific capabilities required by paragraph ''(f)'' (namely, (f)(1), (2), and (3)) as one certification criterion, and that the specific capability to calculate BMI would not be equivalent to one certification criterion.

Based on our proposal to codify all the 2014 Edition EHR certification criteria in § 170.314, we are clarifying that certification to the certification criteria at § 170.314 would occur at the second paragraph level of the regulatory section. The first paragraph level in § 170.314 would be used to organize the certification criteria into categories.

[1] When we refer to CMS's Medicare and Medicaid EHR Incentive Programs Stage 2 proposed rule, we are referring to the NPRM published elsewhere in this issue of the **Federal Register**.

These categories would be: Clinical (§ 170.314(a)); care coordination (§ 170.314(b)); clinical quality measures (§ 170.314(c)); privacy and security (§ 170.314(d)); patient engagement (§ 170.314(e)); public health (§ 170.314(f)); and utilization (§ 170.314(g)). Thus, for this proposed rule, a certification criterion in § 170.314 would be at the second paragraph level and would encompass all of the specific capabilities in the paragraph levels below with, as noted in our discussion of ''applicability,'' an indication if the certification criterion or the specific capabilities within the criterion only apply to one setting (ambulatory or inpatient). For example, we propose to adopt the revised certification criterion for demographics at § 170.314(a)(3) (second paragraph level). The certification criterion includes two specific capabilities at (3)(i) and (ii) (third paragraph level): ''(i)'' enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth (in accordance with the specified standards for race, ethnicity, and preferred language (§ 170.314(3)(i)(A) and (B)); and, ''(ii)'' for the inpatient setting only, enable a user to electronically record, change, and access preliminary cause of death in the event of mortality in accordance with the standard specified in § 170.207(k). Consequently, to meet the proposed certification criterion for demographics, for example, EHR technology designed for the inpatient setting would need to meet § 170.314(a)(3)(i)(A) and (B) and (ii), while EHR technology designed for the ambulatory setting would only need to meet (3)(i)(A) and (B) because the capability at (3)(ii) only applies to the inpatient setting.

3. Explanation and Revision of Terms Used in Certification Criteria

Certain terms are repeatedly used in the proposed 2014 Edition EHR certification criteria. Based on our experience and stakeholder feedback related to how terms in the 2011 Edition EHR certification criteria have been interpreted, we have determined that it is necessary in certain cases to select different terms. The following is a list of terms we repeatedly use in the proposed 2014 Edition EHR certification criteria and the intended meaning for each term.

''User'' is used to mean a health care professional or his or her office staff or a software program or service that would interact directly with the CEHRT. This is essentially the same description that we gave to ''user'' in the S&CC July 2010 final rule (75 FR 44598). We further clarify that, unless expressly stated otherwise, ''user'' does not mean a patient.

''*Record*'' is used to mean the ability to capture and store information in EHR technology. We consider this meaning complementary to and consistent with related terms, namely ''change'' and ''access,'' and their associated capabilities.

''*Change*'' is used to mean the ability to alter or edit information previously recorded in EHR technology. We are replacing the term ''modify'' used in the 2011 Edition EHR certification criteria with ''change.'' Although we interpret both terms to have essentially the same meaning, we believe ''change'' connotes a more plain language meaning as recommended by *plainlanguage.gov*.[2] In certification criteria in which this term is used, we do not intend for it to be interpreted to mean that information previously recorded would be able to be changed without the retention of prior value(s). Rather, a change must be retained as an audited event and in a viewable format that identifies the changed information in a patient's record (similar to how one might see changes represented in a word-processing application). How such changes are displayed is a design decision left to EHR technology developers.

''*Access*'' is used to mean the ability to examine or review information in or through EHR technology. We are proposing to replace the term ''retrieve'' used in the 2011 Edition EHR certification criteria with ''access'' because we believe it is clearer and more accurately expresses the capability we intend for EHR technology to include. We note that some stakeholders had interpreted ''retrieve'' to suggest that the EHR technology also needed to be able to obtain data from external sources. Nevertheless, we interpret both ''access'' and ''retrieve'' to have essentially the same meaning, but note that ''access'' should not be interpreted to include necessarily the capability of obtaining or transferring the data from an external source.

''*Incorporate*'' is used to mean to electronically import, attribute, associate, or link information in EHR technology. With the exception of import, we previously used these terms to describe the ''incorporate'' capability included in certification criteria as illustrated by the capability specified at § 170.302(h)(3). We only propose to revise its unique meaning for the 2014 Edition EHR certification criteria and the purposes of certification to account for the ability to electronically import information.

''*Create*'' is used to mean to electronically produce or generate information. We are proposing to replace the term ''generate'' used in the 2011 Edition EHR certification criteria with ''create.'' We believe ''create'' is clearer and is a better word choice than generate from a plain language perspective.

''*Transmit*'' is used to mean to send from one point to another.

4. New Certification Criteria

In the Permanent Certification Program final rule (76 FR 1302), we described new certification criteria as those that specify capabilities for which the Secretary has not previously adopted certification criteria. We further stated that new certification criteria also include certification criteria that were previously adopted for Complete EHRs or EHR Modules designed for a specific setting and are subsequently adopted for Complete EHRs or EHR Modules designed for a different setting (for example, if the Secretary previously adopted a certification criterion only for Complete EHRs or EHR Modules designed for an ambulatory setting and then subsequently adopts that certification criterion for Complete EHRs or EHR Modules designed for an inpatient setting). Based on our experience trying to appropriately categorize the certification criteria we propose to be part of the 2014 Edition EHR certification criteria, we have determined that our description of new certification criteria needs to be clarified. Accordingly, we list below the factors that we would consider when determining whether a certification criterion is ''new:''

- The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or
- The certification criterion was previously adopted as ''mandatory'' for a particular setting and subsequently adopted as ''mandatory'' or ''optional'' for a different setting.

We propose to adopt new certification criteria that will support new MU objectives and associated measures, the reporting of MU measures, and will enable EHR technology to enhance patient engagement. Some of the new criteria would apply to both ambulatory and inpatient settings, while some certification criteria would only apply to one of the settings or would be new for a particular setting.

[2] *http://www.plainlanguage.gov/howto/wordsuggestions/simplewords.cfm#lm.*

a. Ambulatory and Inpatient Setting

We propose to adopt 8 certification criteria that would be new certification criteria for both the ambulatory and inpatient settings.

• *Electronic notes*

MU Objective
Record electronic notes in patient records.
2014 Edition EHR Certification Criterion § 170.314(a)(9) (Electronic notes)

The HITSC recommended a certification criterion similar to the 2014 Edition EHR certification criterion we propose at § 170.314(a)(9) (with specific reference to ''physician, physician assistant, or nurse practitioner'' electronic notes) to support the MU objective and measure recommended by the HITPC. CMS has not proposed the MU objective and measure for Stage 2, but has requested public comment on whether the objective and measure should be incorporated into Stage 2.

Consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have replaced the terms ''modify'' and ''retrieve'' in the recommended criterion with ''change'' and ''access,'' respectively. Additionally, we are providing the following clarifications for the electronic ''search'' capability. ''Search'' means the ability to search free text and data fields of electronic notes. It also means the ability to search the notes that any licensed health care professional has included within the EHR technology, including the ability to search for information across separate notes rather than just within notes. We believe that this certification criterion would encompass the necessary capabilities to support the performance of the MU objective and measure as discussed in the MU Stage 2 proposed rule.

• *Imaging*

MU Objective
Imaging results and information are accessible through Certified EHR Technology.
2014 Edition EHR Certification Criterion § 170.314(a)(12) (Imaging)

We propose to adopt the 2014 Edition EHR certification criterion at § 170.314(a)(12) to support the performance of the proposed MU objective and measure. We clarify that the phrase ''immediate electronic access'' is intended to mean that a user should be able to electronically access images and their narrative interpretations directly and without, for example, having to login to a separate electronic system or repository. This access could be provided by multiple means, including, but not limited to, ''single sign-on'' and ''secure identity parameter passing.'' We also note that there are data format standards for the transmission of imaging data (Digital Imaging and Communications in Medicine (DICOM)) that we reviewed for this certification criterion, but do not believe that the adoption of these standards is necessary to enable users to electronically access images and their narrative interpretations, as required by this certification criterion. We request public comment regarding whether there are appropriate and necessary standards and implementation specifications for this certification criterion.

• *Family health history*

MU Objective
Record patient family health history as structured data.
2014 Edition EHR Certification Criterion § 170.314(a)(13) (Family health history)

We propose to adopt the 2014 Edition EHR certification criterion at § 170.314(a)(13) to support the performance of the proposed MU objective and measure. In defining family health history, this capability requires, at minimum, the ability to electronically record, change, and access the health history of a patient's first-degree relatives. As proposed in the Stage 2 proposed rule, a first degree relative is a family member who shares about 50 percent of their genes with a particular individual in a family (first degree relatives include parents, offspring, and siblings).

We considered adopting specific standards for this certification criterion, including the HL7 Pedigree standard [3] and the use of Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT®) [4] terms for familial conditions. We seek comments on the maturity and breadth of industry adoption of the HL7 Pedigree standard format for export and import of family health history and the use of SNOMED-CT® terms for familial conditions and their inclusion, where appropriate, on a patient's problem list. We also note that the Surgeon General has produced a tool that can capture, save, and manage family health histories using standard vocabularies and can export the data in eXtensible Markup Language (XML) format.[5] We seek comments on the maturity and breadth of adoption of this tool and its export format.

• *Amendments*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(4) (Amendments)

We propose to adopt the 2014 Edition EHR certification criterion at § 170.314(d)(4). Based on HITPC recommendations submitted to the National Coordinator on July 25, 2011, the HITSC recommended two versions of a draft 2014 Edition EHR certification criterion for amendments. As part of its recommendation, the HITPC (based on the work done by its Privacy and Security Tiger Team) noted that the technical capabilities included in a certification criterion should be ''kept as simple as possible and evolve over time to greater complexity, including potentially greater standardization and automation.'' The HITPC also recommended that this certification criterion be adopted to assist stakeholders by providing them with some of the technical tools to comply with parts of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule requirements specified at 45 CFR 164.526. In addition, the HITPC considered issues related to ''data integrity and quality when a clinician corrects errors that were not reported by the patient or needs to communicate updates to a patient's information.'' We agree with the HITPC and HITSC recommendations, including that a certification criterion should be adopted that provides some of the basic technical tools necessary to comply with the HIPAA Privacy Rule. The proposed certification criterion does not address all of the requirements specified at 45 CFR 164.526 and we note that EHR technology certification is not a substitute for, or guarantee of, HIPAA Privacy Rule compliance. However, we believe that by adopting the proposed certification criterion, EPs, EHs, and CAHs would be provided some of the basic technical tools for compliance with 45 CFR 164.526.

We specifically request comment on whether EHR technology should be

[3] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=8.*

[4] *http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html.*

[5] *https://familyhistory.hhs.gov.*

required to be capable of appending patient supplied information in both free text and scanned format or only one or these methods to be certified to this proposed certification criteria.

• *View, download, and transmit to 3rd party*

MU Objective

EPs

Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

EHs and CAHs

Provide patients the ability to view online, download, and transmit information about a hospital admission.

2014 Edition EHR Certification Criterion

§ 170.314(e)(1) (View, download, and transmit to 3rd party)

Standards

§ 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3–2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639–1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD–10–CM); § 170.207(b)(2) (HCPCS and CPT–4) or § 170.207(b)(3) (ICD–10–PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks)

The HITPC issued a MU recommendation that patients (or their authorized representative(s)) be able to view and download their health information online (i.e., Internet/Web-based). The HITPC recommended that this objective should replace or subsume the objectives for providing patients with timely electronic access to their health information and providing patients with an electronic copy of their health information and hospital discharge instructions upon request. Consistent with these recommendations, the HITSC recommended a certification criterion that framed the capabilities EHR technology would need to include to support this new objective and that, for the 2014 Edition EHR certification criteria, the criterion should replace the certification criteria previously adopted at §§ 170.304(f), 170.304(g), 170.306(d), and 170.306(e) because the new criterion encompassed the data elements required by these capabilities and was seen as a more efficient and effective means for patients to access their health information. We have made several refinements to the recommended certification criterion, while maintaining the critical elements recommended by the HITSC.

In addition to the view and download capabilities recommended by the HITSC, we propose to include a third specific capability in this certification criterion—the ability to transmit a summary care record to a third party. Given that this objective is about making health information more accessible to patients and their caregivers, we believe that patients should have another option available to access their health information. We also believe that in certain cases patients may want to direct their health care provider(s) to transmit a copy of their electronic health information to another entity the patient might use for centralizing their health information (e.g., a personal health record). This additional capability is consistent with, and supports, the right of access standard at 45 CFR 164.524 of the HIPAA Privacy Rule as expanded by section 13405(e) of the HITECH Act with respect to covered entities that use or maintain an EHR on an individual. Section 13405(e) states that, in applying 45 CFR 164.524, an ''individual shall have a right to obtain from [a HIPAA] covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual* * *.'' Coupled with this addition, we have proposed that EHR technology would need to be capable of transmitting a summary care record according to both transport standards we propose to adopt. These transport standards include the two transport specifications developed under the Direct Project [6]: (1) Applicability Statement for Secure Health Transport [7] and (2) External Data Representation (XDR) and Cross-Enterprise Document Media Interchange (XDM) for Direct Messaging.[8] The Applicability Statement for Secure Health Transport specification describes how electronic health information can be securely transported using simple mail transport protocol (SMTP), Secure/Multipurpose Internet Mail Extensions (S/MIME), and X.509 certificates. The XDR and XDM for Direct Messaging specification describes the use of XDR and XDM as a means to transport electronic health information and serve as a bridge between entities using/following Web services and SMTP transport methods. We believe that these transport standards are ideal for these purposes and will make it possible for patients to transmit a copy of their summary care record to the destination of their choice. Additionally, because we have proposed requiring the capability to perform transmissions in accordance with these transport standards (which provide for encryption and integrity protection) in this criterion and in the ''transitions of care—create and transmit summary care record'' certification criterion, we have determined that it is not necessary to include in the 2014 Edition EHR certification criteria the ''encrypting when exchanging'' certification criterion adopted in the 2011 Edition EHR certification criteria (§ 170.302(v)). We believe that to include the 2011 Edition EHR certification criterion would be redundant and that our proposed approach more explicitly ties security to a particular transmission.

At the recommendation of the HITSC, this proposed certification criterion requires that EHR technology certified to this criterion include a ''patient accessible log'' to track the use of the view, download, and transmit capabilities included in this certification criterion (i.e., record the user identification, the user's actions, and the health information viewed, downloaded, or transmitted) and make that information available to the patient. We have required this specific capability within this certification criterion because we believe that it is highly likely numerous EHR Modules could be certified to this criterion without also being certified to the auditable events and tamper resistance certification criterion we propose to adopt at § 170.314(d)(2) due to the proposed policy change we specify in section IV.C.1 below related to EHR Modules and privacy and security. Thus, this express requirement guarantees that an EHR Module certified to this criterion would include the capability to track who has viewed, downloaded, or transmitted to a third party electronic health information and that patients would have access to this information. That being said, we do not intend for this portion of the certification criterion to impose a redundant requirement on EHR technology developers who present a Complete EHR or EHR Module for certification to both this certification criterion and the auditable events and

[6] *http://wiki.directproject.org/Documentation+Library.*

[7] *http://wiki.directproject.org/Applicability+Statement+for+Secure+Health+Transport.*

[8] *http://wiki.directproject.org/XDR+and+XDM+for+Direct+Messaging.*

tamper resistance certification criterion. Accordingly, we provide in paragraph (e)(1)(ii)(B) of § 170.314 that EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of § 170.314 if it is also certified to the certification criterion proposed for adoption at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) of § 170.314 is accessible to the patient. In other words, an EHR technology certified to § 170.314(d)(2) would not need to also include the ''patient accessible log'' capability specified in paragraph (e)(1)(ii)(A) of § 170.314 because it would be capable of logging such events and providing the information to the patient.

We also propose for the ''patient accessible log'' capability to require that the date and time each action occurs be recorded using a system clock that has been synchronized following either Request for Comments (RFC) 1305 Network Time Protocol (NTP) v3 or RFC 5905 Network Time Protocol Version 4: Protocol and Algorithms Specification (NTPv4). These are final standards published by the Internet Engineering Task Force, a voluntary consensus standards body. Having correctly synchronized clocks is an information security best practice and the NTP, especially version 3, has been widely used and implemented since its publication in 1992.[9] RFC 5905 NTPv4 was published in 2010 [10] and is backwards compatible with NTPv3. It does, however, include a modified protocol header to accommodate the Internet Protocol version 6 (IPv6) address family. For the same reasons we discuss here, we have included in the new certification criterion for electronic medication administration proposed for adoption at § 170.314(a)(17) and the auditing standard proposed for adoption at § 170.210(e) this same ''synchronized clocks'' standard because each includes a capability that requires date and time to be recorded. As a general best practice, we highly encourage and expect EHR technology developers that associate date and/or time with capabilities included in certification criteria not specifically mentioned here to utilize a system clock that has been synchronized following NTPv3 or NTPv4. Additionally, the HITSC recommended that we require as a condition of certification other privacy and security oriented capabilities such as single factor authentication and secure download. We did not include these additional capabilities in our proposals because we believe their technical implementations are commonplace and ubiquitous. Thus, there would seem to be little value added by requiring that these capabilities be demonstrated as a condition of certification.

We propose to require EHR technology to be capable of enabling images formatted according to the Digital Imaging and Communications in Medicine (DICOM) standard [11] to be downloaded and transmitted to a third party. We believe this specific capability has the potential to empower patients to play a greater role in their own care coordination and could help assist in reducing the amount of redundant and duplicative imaging-oriented tests performed. In fact, the National Institutes of Health has recently funded activities focused on personally controlled sharing of medical images [12] and published a solicitation notice on the same topic.[13]

We believe that all patients should have an equal opportunity to access their electronic health information without barriers or diminished functionality or quality. Thus, after consultation with the HHS Office for Civil Rights and HHS Office on Disability and reviewing the efforts of other Federal agencies, we propose that the viewing capability must meet Level AA conformance with the most recent set of the Web Content Accessibility Guidelines (WCAG). Federal agencies are considering, or proposing to adopt, WCAG 2.0 Level AA conformance for industries and technology they regulate. The Architectural and Transportation Barriers Compliance Board (Access Board) is considering applying WCAG 2.0 Level AA conformance to Federal agencies and telecommunications accessibility, which apply to telecommunication manufacturers.[14] The Department of Transportation is proposing to require WCAG 2.0 Level AA conformance for air carrier Web sites and airport kiosks.[15]

The WCAG were developed through an open process by the World Wide Web Consortium (W3C [16]).[17] The most recent set of guidelines (WCAG 2.0) were published in 2008 and are organized under 4 central principles with testable ''success criteria'': Perceivable, Operable, Understandable, and Robust.[18] Each guideline offers 3 levels of conformance: A, AA, and AAA. Level A conformance corresponds to the most basic requirements for displaying Web content. Level AA conformance provides for a stronger level of accessibility by requiring conformance with Level A success criteria as well as Level AA specific success criteria. Level AAA conformance comprises the highest level of accessibility within the WCAG guidelines and includes all Level A and Level AA success criteria as well as success criteria unique to Level AAA. We are proposing compliance with Level AA because it provides a stronger level of accessibility and addresses areas of importance to the disabled community that are not included in Level A. For example, success criteria unique to Level AA include specifications of minimum contrast ratios for text and images of text, and a requirement that text can be resized without assistive technology up to 200 percent without loss of content or functionality. In addition to WCAG 2.0 Level AA conformance, we are interested in whether commenters believe additional standards are needed for certification to ensure accessibility for the viewing capability, such as the User Agent Accessibility Guidelines (UAAG).[19] Version 2.0 of the UAAG is designed to align with WCAG 2.0, but is currently only in draft form.

The HITSC recommended that we move to one summary care record standard. We agree with this recommendation and believe that moving to one summary care record standard would lead to increased interoperability and spur innovation. The Consolidated CDA is the most appropriate standard to achieve this goal because it was designed to be simpler and more straightforward to implement and, in relation to this rulemaking, its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS is proposing be available to be populated in a summary care record. Accordingly, we are proposing to require that EHR technology be capable of providing the information that CMS is proposing be required in a summary care record that

[9] *http://www.ietf.org/rfc/rfc1305.txt.*

[10] *http://www.ietf.org/rfc/rfc5905.txt.*

[11] *ftp://medical.nema.org/medical/dicom/2011/.*

[12] *http://report.nih.gov/recovery/investmentreports/ViewARRAInvRpt.aspx?csid=211.*

[13] *https://www.fbo.gov/index?s=opportunity&mode=form&id=ccb2340f4d8711b16f9e625b6b519371&tab=core&_cview=0* [solicitation #: NHLBI–CSB–EB–2012–5–RP].

[14] 76 FR 76640 (December 8, 2011). *http://www.gpo.gov/fdsys/pkg/FR-2011-12-08/pdf/2011-31462.pdf#page=1.*

[15] 76 FR 59307 (September 26, 2011). *http://www.gpo.gov/fdsys/pkg/FR–2011–09–26/pdf/2011–24298.pdf.*

[16] *http://www.w3.org/Consortium/.*

[17] *http://www.w3.org/WAI/intro/wcag.*

[18] *http://www.w3.org/TR/WCAG20/.*

[19] *http://www.w3.org/WAI/intro/uaag.php.*

is provided to patients or their authorized representatives.

In certain instances in § 170.314(e)(1), we propose to require that the capability be demonstrated in accordance with the specified vocabulary standard. These vocabulary standards have been previously adopted or are proposed for adoption in this proposed rule consistent with the recommendations of the HITSC. With the exception of the four standards discussed below (LOINC, ICD–10–CM, ICD–10–PCS, and HCPCS), the vocabulary standards included in this certification criterion are discussed elsewhere in this preamble in connection with the certification criteria where the vocabulary standard is central to the required data or serves a primary purpose (e.g., RxNorm for e-prescribing).

For encounter diagnoses and procedures, we propose the use of ICD–10 (ICD–10–CM and ICD–10–PCS, respectively). We request comment, however, on whether we should be more flexible with this proposed requirement based on any potential extension of the ICD–10 compliance deadline or possible delayed enforcement approach. More specifically, we are interested in whether commenters believe it would be more appropriate to require EHR technology to be certified to a subset of ICD–10; either ICD–9 or ICD–10; or to both ICD–9 and ICD–10 for encounter diagnoses and procedures. We also ask that commenters consider these options when reviewing and commenting on the other proposed certification criteria that include these standards (i.e., § 170.314(a)(3), (b)(2), and (e)(2)). For procedures, we propose to continue to permit a choice for EHR technology certification, either ICD–10–PCS or the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT–4). For outbound messages including laboratory tests, EHR technology must be capable of transmitting the tests performed in LOINC 2.38 to meet this certification criterion and for all other proposed certification criteria that include the capability to transmit laboratory tests in the LOINC 2.38 standard. We propose to adopt the ''view, download, and transmit to 3rd party'' certification criterion at § 170.314(e)(1) and the ICD–10–PCS and ICD–10–CM standards at § 170.207(b)(3) and (m), respectively.

In August 2011, we published an advance notice of proposed rulemaking (ANPRM) (76 FR 48769) to seek public comment on the metadata standards we could propose for adoption in this proposed rule. In the ANPRM, we stated:

> We are considering whether to propose, as a requirement for certification, that EHR technology be capable of applying the metadata standards in the context of the use case selected by the HIT Policy Committee (i.e., when a patient downloads a summary care record from a health care provider's EHR technology or requests for it to be transmitted to their PHR). For example, if a patient seeks to obtain an electronic copy of her health information, her doctor's EHR technology would have to be capable of creating a summary care record and subsequently assigning metadata to the summary care record before the patient receives it.

We noted in the ANPRM that, after reviewing public comments, we would re-consider our proposals and use this proposed rule to seek further public comment on more specific proposals. Given our proposed adoption of solely the Consolidated CDA standard for summary care records and the fact that this standard requires EHR technology developers to follow the requirements specified in the ''US Realm Header'' (section 2.1 of the Consolidated CDA), which includes the metadata elements we were considering for patient identity and provenance, we do not believe that it would be necessary or prudent to propose separate metadata standards at this time. Accordingly, we believe that for the first use case we identified in the ANPRM our policy goals can be accomplished through the adoption of the Consolidated CDA standard. This approach also addresses the HITSC's recommendation for this certification criterion to include ''data provenance'' with any health information that is downloaded. Finally, consistent with public comments on the ANPRM, we are not proposing metadata standards for ''privacy'' and intend to continue to work with the industry to further flesh out what such metadata standards could be. However, we note that one of the metadata elements required by the US Realm Header is the ConfidentialityCode which should be populated with a value from the value set of BasicConfidentialityKind (this value set includes 3 possible values: ''N'' Normal, ''R'' Restricted, and ''V'' Very Restricted). We intend to continue to work with SDOs and other stakeholders on some of the HITSC recommendations discussed in the ANPRM relative to the CDA header. For example, we welcome comment on, and will consider moving from, the use of object identifiers (OIDs) to uniform resource identifiers (URIs).

- *Automated numerator recording*

MU Objective
N/A
2014 Edition EHR Certification Criterion § 170.314(g)(1) (Automated numerator recording)

To complement the ''automated measure calculation'' certification criterion adopted at § 170.302(n) (and now proposed for adoption as a revised certification criterion at § 170.314(g)(2)), we propose to adopt a 2014 Edition EHR certification criterion which would apply solely to EHR Modules that include capabilities for an MU objective with a percentage-based measure. This certification criterion would focus on the EHR Module's capability to automatically record the numerator for those measures. While a Complete EHR would need to be capable of meeting the automated measure calculation certification criterion which requires the capability to accurately calculate MU denominators, we do not believe that it would be practicable for an EHR Module to do the same because, in most cases, an EHR Module would likely be unable to record or have access to an accurate denominator, especially in the case where multiple certified EHR Modules are being used by an EP, EH, or CAH. That said, we believe that EHR Modules presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure should at least be able to readily and accurately record the numerator for those capabilities. Therefore, we propose to adopt this new certification criterion at § 170.314(g)(1).

As noted, a Complete EHR would need to be certified to the proposed automated measure calculation criterion (§ 170.314(g)(2)). We would consider a Complete EHR certified to § 170.314(g)(2) as having met the proposed automated numerator recording certification criterion at § 170.314(g)(1) and, thus, there would be no need for the Complete EHR to be separately certified to § 170.314(g)(1). However, as discussed under section IV.C.2 of this preamble, EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure would need to be certified to this proposed certification criterion. This would not preclude an EHR Module from being certified to the automated measure calculation certification criterion if the EHR Module developer sought such certification. In such instances, similar to our stance on Complete EHR certification to § 170.314(g)(2), there would be no need

for the EHR Module to be separately certified to § 170.314(g)(1).

• *Non-percentage-based measure use report*

MU Objective
N/A
2014 Edition EHR Certification Criterion
§ 170.314(g)(3) (Non-percentage-based measure use report)
Standard
§ 170.210(g) (synchronized clocks)

To further complement the certification criteria proposed for adoption at § 170.314(g)(1) and (g)(2), we propose to adopt a new 2014 Edition EHR certification criterion at § 170.314(g)(3) which would apply to any EHR technology presented for certification that includes capabilities associated with MU objectives and measures that are not percentage based. This certification criterion would focus on a Complete EHR's or EHR Module's capability to record that a user had certain EHR technology capabilities enabled during an EHR reporting period and had used those capabilities to demonstrate MU. We also propose to require that the date and time be recorded according to the ''synchronized clocks'' standard that we explain in more detail in the preamble discussion of the new ''view, download, and transmit to 3rd party'' certification criterion proposed for adoption at § 170.314(e)(1).

In consultation with CMS, we believe that EPs, EHs, and CAHs would benefit from this type of capability being required as a condition of certification. Additionally, we believe that such a capability could provide EPs, EHs, and CAHs with valuable evidence in the event of an MU audit. We propose that any EHR technology presented for certification to any one of the following certification criteria would need to be certified to this certification criterion.

170.314(a)(2)	Drug-drug, drug-allergy interaction checks.
170.314(a)(8)	Clinical decision support.
170.314(a)(10)	Drug-formulary checks.
170.314(a)(14)	Patient lists.
170.314(a)(17)	Electronic medication administration record.
170.314(f)(2)	Transmission to immunization registries.
170.314(f)(4)	Transmission to public health agencies (surveillance).
170.314(f)(6)	Transmission of reportable laboratory tests and values/results.
170.314(f)(8)	Transmission to cancer registries.

EHR technology that is presented for certification to any of these certification criteria would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled and disabled, and/or executed. We intend for the term ''executed'' to apply only to the certification criteria in the table above except those proposed for adoption at § 170.314(a)(2) and (17). The MU measures associated with § 170.314(a)(2) and (17) require that the capabilities CEHRT include be ''enabled'' or ''implemented'' for an entire EHR reporting period. Moreover, they do not require unique action(s) by an EP, EH, or CAH. Last, we clarify that the privacy and security certification criteria proposed for adoption in § 170.314(d) which are associated with the MU objective ''protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities'' and measure which is not percentage based would not be included within the scope of this certification criterion. We do not believe that EHR technology would be able to capture that a security risk analysis was performed by an EP, EH, or CAH except through a manual entry by the EP, EH, or CAH affirming the completion of the risk analysis.

• *Safety-enhanced design*

MU Objective
N/A
2014 Edition EHR Certification Criterion
§ 170.314(g)(4) (Safety-enhanced design)

The International Organization for Standardization (ISO) defines usability as ''[t]he extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.'' [20] Many industry stakeholders have acknowledged that a gap exists between optimal usability and the usability offered by some current EHR technologies. However, to date, little consensus has been reached on what might help close this gap and what role, if any, the Federal government should play related to the usability of EHR technology. In June 2011, the HITPC issued a report to ONC that explored the challenges associated with EHR technology usability and user-centered design (UCD). In its report, the HITPC identified certain ''desired outcomes of improved usability'' including improved safety and reduced cost, clinician frustration, training time, and cognitive load for clinical and non-clinical users alike.

In November 2011, the Institute of Medicine (IOM) released a report titled ''Health IT and Patient Safety: Building Safe Systems for Better Care,'' in which the usability of EHR technology and quality management was often referenced. The IOM noted that ''[w]hile many vendors already have some types of quality management principles and processes in place, not all vendors do and to what standard they are held is unknown.'' Moreover, given this concern, the IOM recommended that ''[t]he Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.''

We fundamentally agree with the sentiment expressed by both the HITPC and the IOM. As we consider the shared goals stated by stakeholders from all sides of this discussion, we believe that a significant first step toward improving overall usability is to focus on the process of UCD. While valid and reliable usability measurements exist, including those specified in NISTIR 7804 ''Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records,'' [21] we are concerned that it would be inappropriate at this juncture for ONC to seek to measure EHR technology in this way. Recognizing that EHR technologies exist and are in use today, we have prioritized eight certification criteria [22] and associated capabilities to which this proposed certification criterion would require UCD to have

[20] ISO 9241–11.

[21] *http://www.nist.gov/healthcare/usability.*

[22] § 170.314(a)(1) (CPOE); § 170.314(a)(2) (Drug-drug, drug-allergy interaction checks); § 170.314(a)(6) (Medication list); § 170.314(a)(7) (Medication allergy list); § 170.314(a)(8) (Clinical decision support); § 170.314(a)(17) (Electronic medication administration record); § 170.314(b)(3) (Electronic prescribing); and § 170.314(b)(4) (Clinical information reconciliation).

been applied. We chose these eight because we believe they pose the greatest risk for patient harm and, therefore, the greatest immediate opportunity for error prevention and user experience improvement. We believe this approach limits this new certification criterion's potential burden while providing for a much needed focus on the application of UCD to medication-related certification criteria.

The methods for how an EHR technology developer could employ UCD are well defined in documents and requirements such as ISO 9241–11, ISO 13407, ISO 16982, and NISTIR 7741. Presently, we believe it is best to enable EHR technology developers to choose their UCD approach and not to prescribe one or more specific UCD processes that would be required to meet this certification criterion. Thus, the use of any one of these processes to apply UCD would meet this certification criterion. Moreover, we acknowledge and expect that EHR technology developers who have already followed UCD in past development efforts for the identified certification criteria would be performing a retrospective analysis to document for the purposes of testing and certification that UCD had been applied to the specified certification criteria. However, if UCD had not been previously applied to capabilities associated with any of the certification criteria proposed, the EHR technology would ultimately need to have such UCD processes applied before it would be able to be certified.

We propose to adopt this certification criterion at § 170.314(g)(4). If we adopt this certification criterion in a final rule, we anticipate that testing [23] to this certification criterion would entail EHR technology developers documenting that their UCD incorporates, in any form or format, all of the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742). We note that with respect to demonstrating compliance with this certification criterion that this information would need to be available to an ONC–ACB for review. This documentation would become a component of the publicly available testing results on which a certification is based (see section IV.D of this preamble for our proposal to make the test results used for certification publicly available).

In addition to our proposed safety-enhanced design certification criterion, we request comment on two other safety-related certification criteria under consideration for adoption by the Secretary.

Quality Systems

The IOM also recommended that we ''[establish] quality management principles and processes in health IT.'' Working with other Federal agencies, we intend to publish a quality management document that is customized for the EHR technology development lifecycle and expresses similar principles to those included in ISO 9001, IEC 62304, ISO 13485, ISO 9001, and 21 CFR 820. The document would provide specific guidance to EHR technology developers on best practices in software design processes in a way that mirrors established quality management systems, but would be customized for the development of EHR technology. We understand that some EHR technology developers already have processes like these in place, but do not believe, especially in light of the IOM recommendation, that the EHR technology industry as a whole consistently follows such processes. We expect that this document would be published around the same time as this proposed rule and would be available for public comment.[24] Accordingly, we are considering including in the final rule an additional certification criterion that would require an EHR technology developer to document how their EHR technology development processes either align with, or deviate from, the quality management principles and processes that would be expressed in the document. We emphasize that this certification criterion would not require EHR technology developers to comply with all of the document's quality management principles and processes in order to be certified. Rather, to satisfy the certification criterion, EHR technology developers would need to review their current processes and document how they do or do not meet principles and processes specified in the document (and where they do not, what alternative processes they use, if any). We expect that this documentation would be submitted as part of testing and would become a component of the publicly available testing results on which a certification is based.

We are considering adopting this additional certification criterion as part of the 2014 Edition EHR certification criteria for three reasons. First, all EHR technology developers that seek certification of their EHR technology would become familiar with quality management processes. Second, the public disclosure of the quality management processes used by EHR technology developers would provide transparency to purchasers and stakeholders, which could inform and improve the development and certification of EHR technology. Last, EHR technology developers' compliance with the certification criterion would establish a foundation for the adoption of a more rigorous certification criterion for quality management processes in the future without placing a significant burden on developers. We request public comment on this additional certification criterion and the feasibility of requiring EHR technology developers to document their current processes.

Patient Safety Events

We are considering adopting a certification criterion (as mandatory or optional) that would require EHR technology to enable a user to generate a file in accordance with the data required by the Agency for Healthcare Research and Quality (AHRQ) Common Format,[25] including the ''Device or Medical/Surgical Supply, including HIT v1.1a.'' [26] The Common Formats are designed to capture information about patient safety events. In line with IOM's recommendations, we believe that requiring this capability for certification could be an essential first step in creating the infrastructure that would support the reporting of potential adverse events involving EHR technology to patient safety organizations (PSOs). We request public comment on whether we should adopt such a certification criterion and what, if any, challenges EHR technology developers would encounter in implementing this capability.

b. Ambulatory Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the ambulatory setting.

- *Secure messaging*

MU Objective
Use secure electronic messaging to communicate with patients on relevant health information.
2014 Edition EHR Certification Criterion
§ 170.314(e)(3) (Ambulatory setting only—secure messaging)

[23] The National Voluntary Laboratory Accreditation Program, as administered by NIST, is responsible for testing under the permanent certification program (''ONC HIT Certification Program'') (76 FR 1278).

[24] The quality management document will be published on ONC's Web site during the public comment period of this proposed rule and notice of its availability will be made through a notice published in the **Federal Register**.

[25] *http://www.pso.ahrq.gov/formats/commonfmt.htm.*

[26] *https://psoppc.org/web/patientsafety/ahrq-common-formats-device-or-medical/surgical-supply-including-hit-device.*

Standard
§ 170.210(f)

The HITSC recommended two versions (based in large part on the work of the Implementation Workgroup and Privacy and Security Workgroup) of the 2014 Edition EHR certification criterion for secure messaging to support the MU objective and measure recommended by the HITPC, and now proposed by CMS. We agree with the direction provided by both recommendations and have merged the two into a refined certification criterion. We have also included what we believe should be the baseline standard in terms of encryption and hashing algorithms used to implement secure messaging. More specifically, we are proposing that only those identified in FIPS 140–2 Annex A be permitted to be used to meet this criterion. As such, we propose to adopt a new standard in § 170.210(f) to refer to FIPS 140–2 Annex A's encryption and hashing algorithms. Additionally, we are proposing, consistent with the HITSC's recommendations, that methods for meeting this certification criterion could include, but would not be limited to, designing EHR technology to meet the following standards: IETF RFC 2246 (TLS 1.0) and SMTP/SMIME as well as implementation specifications such as NIST Special Publication 800–52 (''Guidelines for the Selection and Use of TLS Implementations'') and specifications developed as part of nationwide health information network initiatives. We propose to adopt this new certification criterion at § 170.314(e)(3).

- *Cancer registry*

MU Objective
Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria
§ 170.314(f)(7) (Ambulatory setting only—cancer case information)
§ 170.314(f)(8) (Ambulatory setting only—transmission to cancer registries)
Standards and Implementation Specifications
§ 170.205(i) (HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38)

The HITPC provided recommendations that CMS consider requiring EPs to submit reportable cancer conditions. CMS has proposed this as a new objective and measure for EPs. We propose to adopt two new 2014 Edition EHR certification criteria to enable the performance of the objective and measure with the use of CEHRT. The proposed adoption of two criteria, one focused on the data capture and the other focused on the formatting and transmission of such data in the proposed standards is consistent with the HITSC recommendation to consider splitting the public health certification criteria in this manner. In consultation with the Centers for Disease Control and Prevention (CDC), we propose to adopt HL7 CDA, Release 2 as the content exchange standard. We also propose to adopt SNOMED CT® International Release January 2012 and LOINC version 2.38 as the vocabulary standards. Additionally, we propose to adopt the Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012. This implementation guide was jointly developed by the CDC and the North American Association of Central Cancer Registries (NAACCR) and is available at *http://www.cdc.gov/ehrmeaningfuluse*. CDC will consider comments received on this proposed rule in finalizing the guide. Assuming CDC finalizes the guide, we would consider adopting the final version of the guide in a final rule with consideration of public comment on the appropriateness of the guide for certification.

We propose to adopt these certification criteria at § 170.314(f)(7) and (8). We propose to adopt the HL7 CDA standard and implementation guide at § 170.205(i). We propose to adopt SNOMED CT® International Release January 2012 and LOINC version 2.38 at § 170.207(a)(3) and (g), respectively.

c. Inpatient Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the inpatient setting.

- *Electronic medication administration record*

MU Objective
Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).
2014 Edition EHR Certification Criterion
§ 170.314(a)(17) (Inpatient setting only—electronic medication administration record)
Standard
§ 170.210(g) (synchronized clocks)

The HITSC recommended a new 2014 Edition EHR certification criterion to support the MU objective and measure recommended by the HITPC, now proposed by CMS, for EHs and CAHs to automatically track medications from order to administration. We have refined the recommended certification criterion to clearly state the capabilities that must be tested and certified. The certification criterion continues to reflect the intent of the HITPC and HITSC, including the basic ''rights'' (right patient, right medication, right dose, right route, and right time). It is our intent, consistent with the HITSC's recommendation, to permit a range of acceptable technical solutions for certification. However, we wish to make clear that in order to demonstrate compliance with this certification criterion, EHR technology must enable a user to electronically confirm the ''rights'' in relation to the medication(s) to be administered in combination with an assistive technology (such as bar-coding, location tracking, and radio-frequency identification (RFID)) which provides automated information on the ''rights.'' An electronic ''checklist'' through which a user would manually confirm the ''rights'' without any automated and assistive feedback from EHR technology would not be sufficient to demonstrate compliance with this certification criterion. We believe this clarification and distinction are important because an electronic medication administration record together with some type of assistive technology has been shown to decrease medication errors [27] and it is not our intent to digitize a paper process that would not realize the safety benefits that could be provided with the use of an assistive technology. We propose to adopt this new certification criterion at § 170.314(a)(17) with inclusion of the ''synchronized clocks'' standard as discussed earlier in this preamble under the ''view, download, and transmit to 3rd party'' certification criterion.

- *Electronic prescribing*

MU Objective
Generate and transmit permissible discharge prescriptions electronically (eRx).
2014 Edition EHR Certification Criterion
§ 170.314(b)(3) (Electronic prescribing)
Standards
§ 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release)

In response to the HITPC's recommendation for a new MU Stage 2 objective and measure for e-prescribing

[27] Poon EG, Keohane CA, Yoon CS, et al. (2010) Effect of Bar-Code Technology on the Safety of Medication Administration *New England Journal of Medicine* 362:1698–1707.

of discharge medications by EHs and CAHs (now proposed by CMS), the HITSC recommended a certification criterion for electronic prescribing of discharge medications. As part of the HITSC recommendation, it was recommended that we require as a condition of certification for the inpatient setting that certain HL7 standards be adopted for exchange within a legal entity. We did not accept this part of the recommendation because it is inconsistent with our approach of adopting standards for the electronic exchange of health information between *different* legal entities. We are proposing to adopt for the inpatient setting the same revised electronic prescribing certification criterion we propose to adopt for the ambulatory setting (i.e., we propose to adopt the certification criterion at § 170.314(b)(3) for both settings). We discuss this revised certification criterion in further detail under the ambulatory setting subsection of the revised certification criteria section of this preamble.

• *Transmission of electronic laboratory tests and values/results to ambulatory providers*

MU Objective
Provide structured electronic laboratory results to eligible professionals.
2014 Edition EHR Certification Criterion
§ 170.314(b)(6) (Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers)
Standards and Implementation Specifications
§ 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)); and § 170.207(g) (LOINC version 2.38)

The HITSC recommended a new 2014 Edition EHR certification criterion to support the MU objective and measure recommended by the HITPC for EHs and CAHs to send electronic laboratory tests and values/results to eligible professionals. CMS has not proposed the MU objective and measure for Stage 2, but has requested public comment on whether the objective and measure should be incorporated into Stage 2.

We have refined the recommended certification criterion, primarily to include the standards and implementation guide recommended by the HITSC and HITPC. The HITSC recommended that we consider requiring the Standards and Interoperability Framework Laboratory Results Interface Initiative (S&I Framework LRI).[28] The S&I Framework LRI was created to reduce the variability of ambulatory laboratory interfaces as well as reduce the cost and time to initiate new electronic laboratory tests and values/results interfaces between clinical labs and ambulatory EHR technology. The S&I Framework LRI focused on the identification of a consistent set of data content that would need to be exchanged when laboratory tests and values/results are electronically delivered. We believe that our proposal to require for certification that inpatient EHR technology be capable of creating for transmission laboratory tests and values/results formatted in accordance with the LRI specification could make it more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (i.e., minimal additional configuration and little to no additional/custom mapping) and that the electronic exchange of laboratory tests and values/results would improve.

To further reduce costs and improve the electronic exchange of laboratory tests and values/results, we are building off the HITSC recommendation and are proposing to adopt a revised certification criterion for the ambulatory setting that would require EHR technology to be capable of incorporating laboratory tests and values/results according to the standards and implementation specifications discussed here, including the LRI implementation guide (see discussion of proposed § 170.314(b)(5) under the revised certification criteria section below). We are also proposing to adopt LOINC version 2.38 as the vocabulary standard. The HITPC recommended using LOINC where available and the HITSC expressed agreement with this approach during their deliberations. Moreover, the LRI implementation guide requires the use of LOINC for laboratory tests. With respect to testing and certification for this certification criterion, we expect, among other aspects, that inpatient EHR technology would need to demonstrate its compliance with the ''Common Profile Component'' and other required profiles included within the LRI implementation guide.

We propose to adopt this new certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(6). We propose to adopt the HL7 2.5.1 standard and LRI implementation guide at § 170.205(k), acknowledging that the LRI specification is currently undergoing HL7 balloting. We intend to continue to monitor its progress and anticipate that a completed specification will be available before we publish a final rule. We propose to adopt LOINC version 2.38 at § 170.207(g).

[28] *http://wiki.siframework.org/Lab+Results+Interface+%28LRI%29+Initiative.*

5. Revised Certification Criteria

In the Permanent Certification Program final rule (76 FR 1302) we described revised certification criteria as certification criteria previously adopted by the Secretary that are modified to add, remove, or otherwise alter the specified capabilities and/or the standard(s) or implementation specification(s) referred to by the certification criteria. We also stated that revised certification criteria may also include certification criteria that were previously adopted as optional, but are subsequently adopted as mandatory. Again, based on our experience in trying to appropriately categorize the certification criteria we propose to be part of the 2014 Edition EHR certification criteria we have determined that our description of revised certification criteria needs to be refined. Accordingly, we list below the factors that we would consider when determining whether a certification criterion is ''revised:''

• The certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion;

• The certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion; or

• The certification criterion was previously adopted as ''optional'' for a particular setting and is subsequently adopted as ''mandatory'' for that setting.

To clarify, in some cases, a certification criterion could be both ''revised'' and ''new.'' For example, a previously adopted certification criterion could have been adopted for only the ambulatory setting. Subsequently, we could revise the certification criterion by adding a new capability and making it mandatory for both the ambulatory and inpatient settings. Once adopted, the certification criterion would be ''new'' for the inpatient setting and ''revised'' for the ambulatory setting.

We propose to adopt revised certification criteria that will support proposed revisions to MU objectives and measures and that will increase the interoperability, functionality, utility, safety, and security of EHR technology.

a. Ambulatory and Inpatient Setting

We propose to adopt the following revised certification criteria for both the ambulatory and inpatient settings.

• *Drug-drug, drug-allergy interaction checks*

MU Objective
Implement drug-drug and drug-allergy interaction checks.
2014 Edition EHR Certification Criterion
§ 170.314(a)(2) (Drug-drug, drug-allergy interaction checks)

The HITSC recommended a revised certification criterion for the 2014 Edition EHR certification criteria to eliminate the ability for EHR technology to permit users to adjust drug-allergy interaction checks and to provide additional clarity for the capabilities that EHR technology must demonstrate. The HITSC reasoned that it would be clinically inappropriate to allow users to adjust drug-allergy interaction checks. The HITSC also reasoned that clarity could be provided with additional revisions. The HITSC recommended replacing the term ''real-time'' with ''before the order is executed.'' The HITSC also recommended revising the language to specify that notifications should happen during CPOE. Additionally, the HITSC recommended specifying that the level of severity of the notifications is what can be adjusted. The HITSC also recommended limiting the ability to make adjustments to an identified set of users or available as a system administrative function. Last, the HITSC recommended that drug-allergy contraindications should be interpreted to include adverse reaction contraindications. We agree with all of the HITSC's recommendations. We have revised and refined the language of the HITSC's recommended certification criterion, but otherwise have included all the recommended capabilities. As to the phrase ''identified set of users,'' we clarify that the EHR technology must enable an EP, EH, and CAH to assign only certain users (e.g., system administrator) with the ability to adjust severity levels. In other certification criteria that use the phrase ''identified set of users,'' a similar principle would apply (i.e., assigning the capability to only certain users). We believe this revised language more clearly indicates the intent of the criterion. We propose to adopt this revised certification criterion at § 170.314(a)(2).

• *Demographics*

MU Objective
Record the following demographics: preferred language; gender; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.
2014 Edition EHR Certification Criterion
§ 170.314(a)(3) (Demographics)
Standards
§ 170.207(f)(OMB standards); § 170.207(j) (ISO 639–1:2002); and § 170.207(k) (ICD–10–CM)

The HITSC recommended that we adopt a revised ''demographics'' certification criterion that requires the use of ISO 639–1 as the vocabulary standard for preferred language.[29] We agree with the HITSC's recommendation because it appropriately limits the burden on EHR technology developers since the ISO 639–1 code set which uses an alpha-2 code for language names is roughly 40% that of the ISO 639–2 code set which uses an alpha-3 code. We also propose to adopt ICD–10–CM for recording the preliminary cause of death. We believe that the use of ICD–10–CM will permit additional specificity for this data element. As for the Office of Management and Budget (OMB) standards for the classification of federal data on race and ethnicity, we note that the standard for classifying federal data according to race and ethnicity requires that the option for selecting one or more racial designations be provided. The standard also permits the use of more than the minimum standard categories for race and ethnicity as long as the data can be aggregated to the minimum standard categories, which would be confirmed through the testing and certification processes. We also propose to clarify the reference to the adopted standard as the ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' which was issued on October 30, 1997, as referenced at § 170.207(f). Last, we propose to revise this criterion to require that EHR technology be capable of recording that a patient declined to specify his or her race, ethnicity, and/or preferred language. This proposed revision would ensure inclusion of such patients in the numerator of the MU percentage-based measure. We propose to adopt this revised certification criterion for the 2014 Edition EHR certification criteria at § 170.314(a)(3) and the proposed standards at § 170.207(j) and (k).

[29] *http://www.loc.gov/standards/iso639–2/php/code_list.php*—Also note that The Library of Congress has been designated the ISO 639–2/RA for the purpose of processing requests for alpha-3 language codes comprising the International Standard.

• *Problem list*

MU Objective
Maintain an up-to-date problem list of current and active diagnoses.
2014 Edition EHR Certification Criterion
§ 170.314(a)(5) (Problem list)
Standards
§ 170.207(a)(3) (SNOMED CT® International Release January 2012)

Consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have replaced the terms ''modify'' and ''retrieve'' in the recommended criterion with ''change'' and ''access,'' respectively. Further, consistent with the interpretation we provided in the S&CC July 2010 final rule, we are reiterating and clarifying that ''*longitudinal care*'' is used to mean over an extended period of time. For the ambulatory setting, this would be over multiple office visits. For the inpatient setting, this would be for the duration of an entire hospitalization, which would include the patient moving to different wards or units (e.g., emergency department, intensive care, and cardiology) within the hospital during the hospitalization. The HITSC suggested that we consider longitudinal care to cover multiple hospitalizations, but we believe this could be difficult to achieve and may not offer added value based on the duration of time between a patient's hospitalizations and the reason for the hospitalizations. To note, our clarification of the meaning of longitudinal care applies equally to its use in other certification criteria, such as ''medication list'' and ''medication allergy list.'' If we were to change our interpretation of longitudinal care as suggested by the HITSC, it would apply to these certification criteria as well and could constitute a change in the capabilities included in the criteria, which in turn would cause them to become revised certification criteria. We welcome comments on our interpretation of longitudinal care. We also welcome comments on whether a term other than ''longitudinal care'' could and should be used to express the capability required by this certification criterion and the other referenced certification criteria (''medication list'' and ''medication allergy list''). We understand that the longitudinal care description we use for the purposes of EHR technology certification may differ from the meaning that providers attribute to it, including the meaning given to it by the Longitudinal

Coordination of Care Workgroup within the Standards and Interoperability Framework.[30]

The HITSC recommended that we adopt the appropriate version of SNOMED CT® for the revised criterion. We have determined, and propose to adopt, the International Release January 2012 version of SNOMED CT.® This is the most recent version of the code set.[31] The HITSC also recommended that ICD–9–CM be replaced with ICD–10–CM. We agree that the use of ICD–9–CM should no longer be required due to the pending move to ICD–10–CM. However, we do not believe it would be appropriate to require the use of ICD–10–CM for problem lists. SNOMED CT® (and not ICD–10–CM) will be required for calculation of CQMs. Therefore, we propose that only SNOMED CT® is an appropriate standard for the recording of patient problems in a problem list. This does not, however, preclude the use of ICD–10–CM for the capture and/or transmission of encounter billing diagnoses. We propose to adopt this revised certification criterion for the 2014 Edition EHR certification criteria at § 170.314(a)(5) and the International Release January 2012 version of SNOMED CT® at § 170.207(a)(3).

- *Clinical decision support*

MU Objective
Use clinical decision support to improve performance on high-priority health conditions.
2014 Edition EHR Certification Criterion
§ 170.314(a)(8) (Clinical decision support)
Standard
§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (''Infobutton'') Standard, International Normative Edition 2010)

The HITSC recommended a revised clinical decision support (CDS) certification criterion for the 2014 Edition EHR certification criteria. We have refined the recommended certification criterion to provide a clearer understanding of the capabilities that must be tested and certified and to provide greater flexibility to EHR technology developers in designing EHR technology to meet this proposed certification criterion. We also propose to require the use of the HL7 Context-Aware Knowledge Retrieval (''Infobutton'') Standard, International Normative Edition 2010, for retrieving diagnostic or therapeutic reference information and specifically require the use of CDS with the incorporation of a summary care record.

We have replaced the term ''clinical decision support rule'' used in the 2011 Edition EHR certification criteria and the HITSC recommended criterion with the term ''clinical decision support intervention'' to better align with, and clearly allow for, the variety of decision support mechanisms available that help improve clinical performance and outcomes. A CDS intervention is not simply an alert, notification, or explicit care suggestion. Rather, it should be more broadly interpreted as the user-facing representation of evidence-based clinical guidance. Our goal in clarifying the nomenclature is to focus more on the representation of the guidance (the CDS intervention) that the EHR technology should offer to the user rather than prescribe the form of either the logical representation of the clinical guidance or how the intervention interacts with the user.

Referential sources such as medical texts, primary research articles, and clinical practice guidelines have long been available in electronic form, but the means and manner of accessing them have historically been disconnected from the points in providers' patient care workflows when the immediate availability of the reference sources would optimize clinical decisions. Increasingly, these tools are being made available through links in EHRs, offering information at relevant points within the clinical workflow. The Infobutton standard has been in active use for several years with many reference content vendors now providing their products in this form, and we propose to adopt its most recent edition (International Normative Edition 2010) in order to enable a user to retrieve diagnostic or therapeutic reference information. The use of standard reference information retrieval formats will accelerate the delivery of content to providers and hospitals, and will enhance the flexibility of such implementations because these formats reduce the need to ''hard wire'' the content databases to installed EHR technology. This flexibility allows EPs, EHs, and CAHs more choices and easier migration across content providers, encouraging innovation and competitiveness among these content providers.

We believe it is important for CDS interventions to be triggered when new information is incorporated into EHR technology as a result of a care transition. Therefore, we are proposing that EHR technology enable interventions to be triggered when the specified data elements are incorporated into a summary care record pursuant to the capability specified at § 170.314(b)(1) (transitions of care—incorporate summary care record). We are also considering whether EHR technology should be capable of importing or updating value sets for the expression of CDS vocabulary elements using the HL7 Common Terminology Services, Revision 1, standard. We request comment on industry readiness to adopt this standard and on the benefits it could provide if required as a part of this certification criterion.

Consistent with the HITSC stated intent, for EHR technology to be certified to this criterion it must be capable of providing interventions and the reference resources in paragraph (a)(8)(ii)(A) of § 170.314 by leveraging each one or any combination of the patient-specific data elements listed in paragraphs (a)(8)(i) and (ii) of § 170.314 as well as one or any combination of the user context data points listed in paragraph (a)(8)(iii)(A) of § 170.314. EHR technology must also be capable of generating interventions automatically and electronically when a user is interacting with the EHR technology. Last, the HITSC recommended that the source attributes of suggested interventions be displayed or available for users. We agree that this capability is important, but believe further clarification is necessary regarding what types of information must be provided for EHR technology to meet this criterion. We believe that, at a minimum, a user should be able to review the: bibliographic citation (i.e., the clinical research/guideline) including publication; developer of the intervention (i.e., the person or entity who translated the intervention from a clinical guideline into electronic form, for example, Company XYZ or University ABC); funding source of the intervention development; and release and, if applicable, revision date of the intervention. The availability of this information will enable the user to fully evaluate the intervention. The availability of this information will also enhance the transparency of all CDS interventions, and thus improve their utility to healthcare professionals and patients.

We propose to adopt this revised certification criterion at § 170.314(a)(8) and the Infobutton standard at § 170.204(b)(1).

- *Patient-specific education resources*

MU Objective

[30] *http://wiki.siframework.org/Longitudinal+Coordination+of+Care+WG.*

[31] *http://www.nlm.nih.gov/research/umls/licensedcontent/snomedctfiles.html.*

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.
2014 Edition EHR Certification Criterion
§ 170.314(a)(16) (Patient-specific education resources)
Standard
§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010)

We propose to adopt a revised 2014 Edition EHR certification criterion that does not have the language ''as well as provide such resources to the patient'' at the end of the paragraph. This language is in the 2011 Edition EHR certification criterion, but is redundant of the capability expressed at the beginning of the paragraph. Additionally, we propose to adopt the HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010, as the required standard. Infobutton is being increasingly used by more providers to electronically identify and provide patient-specific education resources. Therefore, we believe it is appropriate now to require EHR technology to enable a user to identify and provide patient-specific education resources based on the specified data elements and in accordance with Infobutton. We propose to adopt this revised certification criterion at § 170.314(a)(16) and the Infobutton standard at § 170.204(b)(1).

- *Transitions of care*

MU Objective
The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.
2014 Edition EHR Certification Criteria
§ 170.314(b)(1) (Incorporate summary of care record)
§ 170.314(b)(2) (Create and transmit summary care record)
Standards
§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639–1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED–CT® International Release January 2012); § 170.207(m) (ICD–10–CM); § 170.207(b)(2) (HCPCS and CPT–4) or § 170.207(b)(3) (ICD–10–PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); and § 170.202(a)(1) (Applicability Statement for Secure Health Transport); § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.202(a)(3) (SOAP–Based Secure Transport RTM version 1.0)

The HITSC recommended a merged revised certification criterion for the 2014 Edition EHR certification criteria that would be generally applicable to both the ambulatory and inpatient settings, with a deviation based on the setting-specific information that would be included in the summary care record. We have made refinements to the recommended certification criterion. We believe that the criterion should be split into two separate certification criteria based on the capabilities required. We base this revision on stakeholder feedback received after the publication of the S&CC July 2010 final rule, which explained that (especially for inpatient settings) two different EHR technologies are sometimes used to perform the capabilities of incorporation and creation of a summary care record. Consequently, adopting two separate certification criteria provides developers greater flexibility for certification. The first proposed certification criterion would require EHR technology to be able to incorporate a summary care record formatted according to the Consolidated CDA, and the second certification criterion would require that EHR technology be capable of generating and transmitting a summary care record in accordance with the Consolidated CDA, with certain specified vocabulary standards, and two specified transport standards.

For the same reasons we discussed for the new ''view, download, and transmit to 3rd party'' certification criterion (§ 170.314(e)(1)), we believe that adopting the Consolidated CDA for this certification criterion is advantageous since its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS is proposing be available to be populated in a summary care record. We recognize that care plan, additional care team members, referring or transitioning provider's name and contact information as well as certain hospital discharge information are not explicitly required to be captured by separate certification criteria, unlike most other data elements included in the clinical summary. The ability to capture these data elements is both implicit and necessary to satisfy this certification criterion (as well as the other certification criteria that rely on the same data). Therefore, we considered, but have not proposed, adopting separate data capture certification criteria for each of these data elements in order to make it clear that they are required to be captured. We request public comment on whether in the final rule we should create separate certification criteria for all of these data elements. For certain other data elements in § 170.314(b)(2), we propose to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard. These vocabulary standards have been previously adopted or are proposed for adoption in this proposed rule consistent with the recommendations of the HITSC. Additionally, we request public comment on whether we should require, as part of the ''incorporate summary care record'' certification criterion proposed at § 170.314(b)(1), that EHR technology be able to perform some type of demographic matching or verification between the patient in the EHR technology and the summary care record about to be incorporated. This would help prevent two different patients summary care records from being combined.

As with the ''view, download, and transmit to 3rd party'' certification criterion, we are proposing that EHR technology be capable of transmitting a summary care record according to both the transport standards we propose to adopt to enable directed exchange. We believe the use of these standards is a critical first step in achieving a common means of transporting health information to support MU and future exchange needs. For this certification criterion, we also propose to adopt as an optional standard at § 170.202(a)(3) the SOAP–Based Secure Transport RTM version 1.0 [32] which was developed under the nationwide health information network Exchange Initiative and to which we believe EHR technology should be able to be certified. We believe including this option provides added flexibility to those EPs, EHs, or CAHs that may seek to use EHR technology with the ability to transmit health information using SOAP as a transport standard in addition to SMTP to meet MU. While we would only permit EHR technology to be certified to these two transport

[32] *http://modularspecs.siframework.org/NwHIN+SOAP+Based+Secure+Transport+Artifacts.*

standards, we intend to monitor innovation around transport and would consider including additional transport standards, such as a RESTful implementation, in this certification criterion. The inclusion of additional standards in this certification criterion would permit EHR technology to be certified to added transport standard(s) and could ultimately enable EPs, EHs, and CAHs to meet MU using EHR technology certified with the added transport standard(s).

In deciding whether additional standards are appropriate for inclusion, we would seek the HITSC's recommendation on whether a new transport standard should be adopted. We expect that the HITSC would consider, among other factors, whether the standard is ''open'' or non-proprietary, the public comment processes involved in its development, and any pilot testing completed/results. If the HITSC were to recommend that we adopt an additional transport standard, we believe that it should be designated as optional (consistent with our discussion at 75 FR 44599) and that we would likely pursue interim final rulemaking with comment to adopt the transport standard, which would enable EHR technology to be expeditiously certified to the transport standard and EPs, EHs, and CAHs to subsequently use EHR technology certified to this added transport standard to meet MU.

We welcome comments on whether equivalent alternative transport standards exist to the ones we propose to exclusively permit for certification. We also welcome comment on our proposed approaches for deciding whether additional transport standards are appropriate and for adopting any such standards through interim final rulemaking with comment. Additionally, in the context of the proposed limitations included as part of the proposed MU Stage 2 measure associated with this objective (which is percentage-based), we request public comment on any difficulties EHR technology developers might face in determining the numerator and denominator values to demonstrate compliance with the automated numerator calculation or automated measure calculation certification criteria we propose to adopt.

We propose to adopt these revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(1) and (2).

- *Clinical information reconciliation*

MU Objective
The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.
2014 Edition EHR Certification Criterion
§ 170.314(b)(4) (Clinical information reconciliation)

In the S&CC January 2010 interim final rule, we adopted a certification criterion for medication reconciliation that stated ''[e]lectronically complete medication reconciliation of two or more medication lists by comparing and merging into a single medication list that can be electronically displayed in real-time.'' In response to public comments requesting additional clarity and expressing concerns that EHR technology should not automatically (i.e., without any human intervention) be required to perform this capability, we revised this certification criterion (adopted at § 170.302(j) in the S&CC July 2010 final rule) to say ''[e]nable a user to electronically compare two or more medication lists.''

At the end of one of our responses to comments in the S&CC July 2010 final rule, we stated ''[w]e do, however, see great promise in making this capability more comprehensive and anticipate exploring ways to improve the utility of this capability before we adopt a subsequent round of certification criteria'' (75 FR 44613). We now propose to revise this certification criterion and adopt as part of the 2014 Edition EHR certification criteria an expanded version that focuses on the reconciliation of data elements in each of a patient's medication, problem, and medication allergy lists. We believe that EHR technology can be designed to assist users in remarkable ways and that reconciling information from multiple sources in a way that is assistive to a user is something at which EHR technology should excel. We also believe that with an increased focus on care coordination and use of CDS for advanced care processes, it will be significantly more important for EPs, EHs, and CAHs to have accurate and updated medication, problem, and medication allergy lists.

Accordingly, we propose a revised certification criterion which we are labeling as ''clinical information reconciliation'' to express three specific capabilities that EHR technology would need to include. First, EHR technology would need to be able to electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date of the information. For example, when assisting a user to reconcile a medication list, the EHR technology would need to display the medication(s) and, at a minimum, the source of medications (e.g., ''patient'' or ''summary care record from XYZ'') and the last modification date of the information associated with those medications. The second medication source in this example would be the current medication list the EHR technology maintains for the patient. The second specific capability EHR technology would need to include would be to enable a user to merge and remove individual data elements. For example, if a medication from source #1 and a medication from source #2 were the same, the user would be able to use EHR technology to merge such medications into a single representation. While not required or expected for certification, this capability could be designed to automatically suggest to the user which medications could be merged or removed. The third and final specific capability EHR technology would need to include would be to enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the patient's medication, problem, and/or medication allergy list. Per comments on our prior rules, we want to make clear that EHR technology's role is to be assistive and not to determine without human judgment which data elements should be reconciled. Thus, this third specific capability would require EHR technology to present a final set of merged data elements for a user to validate and confirm before updating the prior list. Finally, we request public comment on whether as part of this certification criterion we should require EHR technology to perform some type of demographic matching or verification between the data sources used. This would help prevent two different patients' clinical information from being reconciled. We propose to adopt this revised certification criterion at § 170.314(b)(4).

- *Incorporate laboratory tests and values/results*

MU Objective
Incorporate clinical laboratory test results into Certified EHR Technology as structured data.
2014 Edition EHR Certification Criterion
§ 170.314(b)(5) (Incorporate laboratory tests and values/results)
Standards and Implementation Specifications

§ 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)); and § 170.207(g) (LOINC version 2.38)

The HITSC did not recommend that we revise the incorporate laboratory test results certification criterion (adopted as part of the 2011 Edition EHR certification criteria at 45 CFR 170.302(h)). We believe, however, that we should leverage the significant progress made by the S&I Framework LRI discussed under the proposed new certification criterion for the transmission of electronic laboratory tests and values/results to ambulatory providers (§ 170.314(b)(6)). This can be achieved by proposing revisions to this certification criterion for the ambulatory setting. By requiring ambulatory EHR technology to be capable of receiving laboratory tests and values/results formatted in accordance with the HL7 2.5.1 standard and the LRI implementation guide, it would be significantly easier and more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (i.e., minimal additional configuration and little to no additional/custom mapping). Moreover, it would increase the likelihood that data would be properly incorporated into ambulatory EHR technology upon receipt and thus, facilitate the subsequent use of the data by the EHR technology for other purposes, such as CDS. We propose to adopt LOINC version 2.38 as the vocabulary standard, because the LRI implementation guide requires the use of LOINC for laboratory tests. We request public comment on whether the proposed standards for the ambulatory setting should also apply for the inpatient setting and whether the LRI specification (even though it was developed for an ambulatory setting) is generalizable to an inpatient setting and could be adopted for certification for that setting as well. Besides the proposed revisions discussed, we have used the term ''incorporate'' to replace the terms ''attribute,'' ''associate,'' and ''link'' which were used in the 2011 Edition EHR certification criterion.

We propose to adopt this revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(5). We propose to adopt the HL7 2.5.1 standard and LRI implementation guide at § 170.205(k), acknowledging that the LRI specification is currently undergoing HL7 balloting. We intend to continue to monitor its progress and anticipate that a completed specification will be available before we publish a final rule. We propose to adopt LOINC version 2.38 at § 170.207(g).

- *Clinical quality measures*

MU Objective
N/A
2014 Edition EHR Certification Criteria
§ 170.314(c)(1) (Clinical quality measures—capture and export)
§ 170.314(c)(2) (Clinical quality measures—incorporate and calculate)
§ 170.314(c)(3) (Clinical quality measures—reporting)
Standard
§ 170.204(c) (NQF Quality Data Model)

The HITSC recommended certain vocabularies and codes sets for inclusion in the Quality Data Model (QDM),[33] but did not recommend CQM certification criteria or offer recommendations for the certification of CQMs. For the 2014 Edition EHR certification criteria, we propose to revise previously adopted CQM certification criteria for the ambulatory and inpatient settings to specify more explicitly the capabilities EHR technology would need to include, focusing on:

- *Data capture*—The capability of EHR technology to record the data that would be required in order to calculate CQMs.
- *Export*—The capability of EHR technology to create a data file that can be incorporated by another EHR technology to calculate CQMs.
- *Calculate*—The capability of EHR technology to incorporate data (from other EHR technology where necessary) and correctly calculate the result for CQMs.
- *Reporting*—The capability of EHR technology to create a standard data file that can be electronically accepted by CMS.

By explicitly separating the certification of CQMs into these discrete criteria, we believe that user experiences relative to CQMs can be enhanced, the burden of capturing data elements necessary for CQMs can be reduced, and ultimately, EPs, EHs, and CAHs would be better positioned to assess in real-time the quality of care they provide.

Data Capture

Prior to the EHR Incentive Programs, measure stewards did not routinely or traditionally specify CQMs with consideration of EHR technology and its capacity to capture certain data. To assist in the effort of preparing CQMs in a more uniform manner, the National Quality Forum (NQF), under contract with CMS, created the QDM which today serves as the information model from which new CQMs are specified. Because older CQMs were not specified as ''EHR-ready'' when initially developed, they specify certain data capture requirements that most EHR technologies cannot perform (or do not perform in any structured way) as well as constructs that would still require human intervention or judgment (i.e., ''chart abstraction''). Despite the best efforts to ''re-tool'' older measures for inclusion at the beginning of the EHR Incentive Programs, we now understand that the CQMs required for certification as part of the S&CC July 2010 final rule did not, in some cases, adequately reflect a pure ''EHR-ready'' CQM. We have been informed that as a result EHR technology developers created new data fields and/or advised their customers to use specified (and in some cases alternative and atypical) workflows, templates, or form elements to capture these data elements in a consistent manner that would enable such data to be captured for a CQM calculation.

To build on past feedback and lessons learned, we have, with CMS, jointly conducted extensive research, consulted with subject matter experts, and received recommendations (on CQMs generally) from the HITPC and HITSC. We have sought to determine how to best address the difference between the data capture capabilities we believe most EHR technologies can reasonably perform and the requirements that measure stewards have specified in CQMs. This work has led us to believe that a more explicit and extensible approach for CQM certification is required, an approach that would be able to support the CQMs proposed for MU Stages 1 and 2 beginning in FY/CY 2014 as well as CQMs adopted for future MU stages.

The CQM lifecycle starts with the determination of data elements to be captured and the subsequent capture of clinical or demographic data. Thus, the first specific capability we propose for CQM certification (§ 170.314(c)(1)(i)) focuses on the capability of EHR technology to electronically record all of the data elements that are represented in the QDM. More specifically, EHR technology would need to be able to record data in some representation that can be associated with the categories, states, and attributes represented by the QDM. As a simple example, EHR technology would need to be able to record a representation of ''Medication *active*'' or ''Problem *active*'' where the first term represents the QDM category and the second represents the QDM

[33] Quality Data Model—National Quality Forum: *http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx.*

''state of being.'' In certain cases, such as in the prior example with ''Problem *active,*'' the data capture necessary is already specified by another certification criterion proposed for adoption as part of the 2014 Edition EHR certification criteria (i.e., § 170.314(a)(5) to record active problems). However, in other cases an EHR technology developer would need to review the QDM to ensure the EHR technology presented for certification captures data elements that are not explicitly required to be recorded in other proposed certification criteria. Because the QDM is agnostic to health care settings (e.g., ambulatory and inpatient settings) and all of the CQMs ultimately adopted by CMS in a final rule would be based on the QDM, we do not believe that it would be necessary or possible to propose specific separate ambulatory and inpatient setting certification requirements as we have with other proposed certification criteria. Thus, all EHR technology regardless of the setting for which it is designed would need to meet § 170.314(c)(1)(i) if it is presented for certification to this certification criterion. Furthermore, because data capture is fundamental to the eventual calculation of CQMs, we have proposed an EP, EH, or CAH would need to have EHR technology certified to § 170.314(c)(1) in order to have EHR technology that meets the definition of a Base EHR (discussed later in this preamble).

We recognize that EPs, EHs, and CAHs may employ many methods to capture the information required by CQMs and we do not intend for this certification criterion to imply that EHR technology developers would need to include manual data entry requirements if such data can be easily obtained from other electronic sources. For example, we anticipate that a patient's smoking status could be captured through a variety of approaches such as an ''app'' on a mobile phone, a portal, personal health record (PHR), from a patient registration kiosk, or practice management system. Regardless of the data's origin or source system, an EHR technology developer would need to show for certification that its EHR technology can electronically record a representation of that data. Moreover, we do not require for certification that data must be recorded according to a specific vocabulary standard, in recognition of, and to accommodate, environments in which local codes and terminologies have been used or where the data may originate from another electronic source. We do, however, expect that wherever possible, EHR technology developers will use standard vocabularies as this will minimize the need for mapping processes that will require development and maintenance. As described below, we expect that exported quality data would be formatted according to the standard vocabularies in the QDM, where applicable.

Alternative Data Capture Certification Options Considered

The above proposal for data capture represents the certification option that best describes the capabilities that EHR technology would need to include in order to capture the data required for the EHR Incentive Programs CQM proposals from CMS. We recognize that this option may be a suboptimal long-term solution—compared to one that can fundamentally reshape the path measure stewards take to develop ''EHR-ready'' CQMs. Through our work with CMS, it has become clear that gaps still remain between the data capture expectations of the CQMs included by CMS in its Stage 2 proposed rule and the capabilities of EHR technology. While the QDM was created in order to facilitate the development of ''EHR-ready'' CQMs, it is a model that reflects the data representation of CQMs and does not consider whether a given data type would or should be captured by EHR technology. We recognize that the gap between the data defined by the QDM and the data traditionally captured in EHR technology is, in some areas, broad and we request comments regarding (1) Industry readiness for the expansion of EHR technology data capture; (2) how this would impact system quality, usability, safety, and workflow; and (3) how long the industry believes it would take to close this gap. Additionally, we recognize that some specialty-focused EHR technologies may not need to capture all of the data that the QDM describes. We request public comment regarding how certification can accommodate specialty EHR technology developers so that they would not have to take on development work (solely to get certified) for functionality that their customers may not require.

We believe that there are alternative options to our proposal and request public comment with respect to whether we should pursue one or more of the alternative approaches below for certification in the final rule.

- *CQM-by-CQM Data Capture:* Our proposed data capture certification criterion specifies that EHR technology must be able to capture all of the data elements represented in the QDM. As an alternative to our proposal, we considered an approach to certification for data capture that would be based on the data elements reflected in the individual CQMs selected by CMS instead of the entire QDM. When EHR technology is presented for certification for data capture, the developer would identify the specific CQMs that the technology is capable of supporting, and the technology must capture each and every data element reflected in those CQMs in order to be certified. For example, if a developer presents for certification EHR technology designed for an inpatient (e.g., emergency department) setting that would support the hospital quality measures NQF 0495 and 0497, the technology would have to demonstrate that it could capture all of the data elements included in those measures. An EHR technology developer would design its EHR technology to capture the data elements for those CQMs it believed its EHR technology would need to support for the types of providers to which it markets its EHR technology. We believe this approach may be advantageous because it poses a lower initial burden for EHR technology developers. But it also has its disadvantages because it could lead to a void in the market for EHR technology that would support certain CQMs that EPs, EHs and CAHs would need to report beginning in 2014. We request public comment on whether we should take this approach instead of our proposal on certification for data capture.

- *Explicit Certification Criteria:* In some cases, we recognize that while not required for certification, many EHR technologies already capture data elements included in the QDM. For example, inactive medical problems may be captured and represented as past medical history. For these cases, we considered and believe that it would be clearer (and easier for EHR technology developers) if we were to either add specific CQM data capture requirements to already existing certification criteria or adopt new certification criteria in order to explicitly require the data that is specified by the QDM to be captured. In other cases, despite a measure steward specifying that certain data capture occur, we are unaware of a consistent or established method with which EHRs capture certain information. For example, most EHR technology of which we are aware does not consistently capture why a particular medication was not prescribed, nor do they systematically make a distinction between ''patient reason,'' ''system reason,'' and ''medical

reason.'' We request public comment on whether this approach would be preferred, which certification criteria should be expanded, and where new certification criteria would be appropriate. We believe this approach could also ensure when EHR Modules are used in combination to meet the definition of CEHRT that all of the data necessary to capture for CQM calculations would be electronically available.

• *CQM Exclusions:* Our research indicates that CQM exclusions represent the majority of CQM data that are expected by measure stewards to be captured or represented in EHR technology but are not. In cases where a CQM specifies a negation exclusion,[34] we propose that EHR technology would not be required to capture the ''reason'' justification attribute of any data element in an encoded way. Rather, we would permit ''reason'' to allow for free text entries. For calculation and reporting purposes, the presence of text in the ''reason'' field may be used as a proxy for any ''reason'' attribute. We request public comment regarding the impact this flexibility would have on the accuracy of CQM reporting.

• *Constrain the QDM:* Working with CMS and NQF, we have considered the creation of a draft ''style guide'' to constrain the QDM in a manner that would identify a subset of data types and their associated attributes that we believe EHR technology could reasonably be expected to be captured. Measure stewards would then need to constrain CQMs to reference only data elements that are within the boundaries of the data types/attribute pairs expressed in the constrained QDM style guide. Such CQMs would be identified as ''2014-EHR-ready'' while other CQMs would not. We would subsequently collaborate with CMS to remove CQMs that do not qualify as ''2014-EHR-ready'' from the EHR Incentive Programs requirements and, as discussed above, could add certification criteria in our final rule in order to explicitly define the data types and attributes that will be necessary for complete CQM data capture according to the constrained QDM style guide. This option would serve to align the capabilities of EHR technology with the expectations of CQMs and would provide a solid path toward an additional alignment of CQMs with CDS for future stages of the EHR Incentive Programs. CDS can provide the interactive capability that would be required in order to capture the granular exclusion data that is expected today by many CQMs. With the inclusion of CDS in the clinical quality improvement strategy for future stages of this program, we expect to be able to remove the flexibility outlined above for the capture of ''reason'' attributes. This would improve the accuracy of CQMs while retaining optimal clinical workflow, as CDS would ideally be engaged to prompt for this information only where indicated, rather than in all cases. We seek public comment, especially from measure stewards, as to the difficulty and timeliness with which CQMs could be re-specified in accordance with the constrained QDM style guide.

• *Explicit Data Capture List:* Another approach we considered instead of specifying the QDM would be to publish the complete list of unique data elements that would be required for data capture in order to be assured that CQMs could be calculated. The advantage of this list is that it would provide explicit guidance to EHR technology developers and could potentially reduce the upfront work that each individual EHR technology developer would need to do in order to prepare their EHR technology for certification.

Data Export

Equally fundamental to data capture is the ability of EHR technology to put the data that has been captured to use. Thus, we believe that it is prudent to propose that EHR technology presented for certification not only be able to capture data for CQMs based on the QDM, but be able to export this data as it is represented in the QDM in the event that an EP, EH, or CAH chooses to use another certified EHR Module to perform the calculation of CQM results—which is why we include the export capability as part of the certification criterion proposed at § 170.314(c)(1). We recognize that in many care delivery settings, CQM calculation and reporting may occur through the use of different EHR technologies from those used to capture data. For example, certified EHR Module #1 may be part of an EH's Base EHR, but the EH may use certified EHR Module #2 to perform the analytics needed for CQM calculation and reporting. By requiring that all EHR technology presented for certification capture CQM data and also export the data, we believe EPs, EHs, and CAHs would be provided the flexibility to use separate EHR Modules for calculation and/or reporting, even if they have purchased or licensed an integrated solution.

We believe this approach preserves portability and flexibility and offers the EPs, EHs, and CAHs the option of using regional or national CQM calculation and/or reporting solutions, such as registries or other types of data intermediaries that could obtain modular certification for the services that they offer. We are unaware of the existence of a widely adopted standard to export captured CQM data. Thus, for certification, it would be at the EHR technology developer's discretion to determine the format of the data file that its EHR technology would be able to produce as well as whether the data would be exported in aggregate or by individual patients. While this scenario is not ideal, we believe that it could also create a market in which EHR Modules focused on CQM calculation (and reporting) could be designed to exploit the disparate data files that EHR technologies produce. We request comment on whether any standards (e.g., QRDA category 1 or 2, or Consolidated CDA) would be adequate for CQM data export as well as whether Complete EHRs (that by definition would include calculation and reporting capabilities) should be required to be capable of data export.

Calculation

In the S&CC July 2010 final rule (75 FR 44611) and finalized in the respective certification program rules (75 FR 36170, 76 FR 1276), we discussed requirements that ONC–Authorized Testing and Certification Bodies (ONC–ATCBs) and ONC–Authorized Certification Bodies (ONC–ACBs) must report to ONC the CQMs to which a Complete EHR or EHR Module has been certified and that ONC–ATCBs and ONC–ACBs must ensure that Complete EHR and EHR Module developers include on their Web sites and in all marketing materials, communications statements, and other assertions related to a Complete EHR or EHR Module's certification the CQMs to which the Complete EHR or EHR Module was certified. These requirements can be found at § 170.423(h)(5) and (k)(1)(ii) and

[34] A negation exclusion or exception is a factor that removes a given patient from the denominator of a CQM with a statement about why a given event or intervention did not occur. For example, a CQM may state that all patients with X condition must have Y intervention, except patients who did not receive the intervention for reason Z. A CQM may state that all patients over the age of 6 months should have an influenza vaccine between October and February (Y intervention), except patients with allergy to egg albumin (reason Z–1) or patients who decline vaccination (reason Z–2). In some measures, the unit of analysis is not a patient, but an encounter or a procedure. In such measures the exclusion or exception can apply to individual patient factors or factors affecting the specific unit of analysis. Additionally, exclusions for ratio measures can also remove a patient from the numerator.

§ 170.523(f)(5) and (k)(1)(ii). The posting of this information on the Certified HIT Products List (CHPL) combined with Complete EHR and EHR Module developers making this information available in association with their certified Complete EHRs and EHR Modules provides both transparency and useful information for potential purchasers (e.g., EPs, EHs, and CAHs) that are trying to determine what EHR technology best meets their needs.

In the S&CC July 2010 final rule, we adopted at § 170.304(j) the CQM certification criterion for EHR technology designed for an ambulatory setting. As expressed in the S&CC July 2010 final rule and in ONC FAQ 9–10–012 [35] and CMS FAQ 10649,[36] this certification criterion was treated as a threshold. In other words, if an EHR technology included all 6 of the core CQMs specified by CMS and at least 3 other additional CQMs, it could meet the certification criterion, and if there was an additional CQM that the EHR technology included, CMS permitted the EP to report on that CQM, even though it was not expressly listed on the CHPL. Some EHR technology developers sought certification to only the 9 CQMs required to meet the threshold, and thus the criterion, but subsequently communicated to EPs that their EHR technology was certified for all of the CQMs it included. Other EHR technology developers took the opposite approach and sought certification for more than the 9 CQMs. Those EHR technologies were consequently listed on the CHPL as being certified to more CQMs. We seek to eliminate this disparity by proposing that EHR technology presented for certification to § 170.314(c)(2) would need to be certified to each and every individual CQM for which the EHR technology developer seeks to indicate its EHR technology is certified. We believe this approach provides transparency and greater certainty regarding the ''certified CQMs'' that EHR technology includes, given CMS' proposal to only permit EPs, EHs, and CAHs to report on CQMs with EHR technology that has been certified to capture and calculate those CQMs.

As noted above, we anticipate that in many cases the calculation of CQMs could be performed by an EHR technology that is different from the one that was certified to capture the CQM data. For this reason, we propose a separate certification criterion for the calculation of CQMs. We believe this separation enables market flexibility and creates room for innovation. The certification criterion we propose includes two specific capabilities. The first capability would require that EHR technology presented for certification would need to be able to electronically incorporate all of the data elements necessary to calculate CQMs for which it is to be certified. In cases where an EHR technology developer presents an EHR technology for certification that is also being certified to § 170.314(c)(1) and (3) (i.e., the EHR technology would be able to do all three capabilities: Capture, calculate, and report), we do not believe that it would be necessary for an EHR technology to demonstrate its compliance to § 170.314(c)(2)(i). However, we specifically request public comment on this assumption before we will add this exception to the certification criterion, which we may do in our final rule. In all other cases, an EHR technology would need to meet § 170.314(c)(2)(i) and (ii).

The second specific capability, § 170.314(c)(2)(ii), focuses on an EHR technology's ability to calculate each CQM for which it is presented for certification. For example, if an EHR technology is presented for certification with test results for 20 CQMs, then the most CQMs that could be included as part of its certification and listed on the CHPL would be 20. Furthermore, an ONC–ACB would need to review each of the 20 CQMs for which the EHR technology is presented for certification and make a separate determination as to whether the calculation test results for each CQM are satisfactory and accurate. It is our expectation that EHR technology certified to this criterion would be capable of accurately, and without errors, calculating CQMs. We expect the accuracy of these calculations would be verified through thorough testing. We request public comment, especially from measure stewards and EHR technology developers, on the best way for CQM test data sets to be developed.

Given the separation between capture and calculation, combined with CMS's policy that only CQMs calculated by CEHRT would count for attestation and electronic submission, we could foresee a scenario where an EP's, EH's, or CAH's CEHRT (composed of certified EHR Modules—perhaps from different vendors) could capture more data than it is certified to calculate. We recognize that this scenario could present challenges for providers who possess licenses to such mismatched certified EHR modules and we request comment regarding this scenario and its likelihood and any additional methods we could employ to mitigate this risk.

Reporting

The last CQM-oriented certification criterion we propose would require EHR technology to enable a user to electronically create for transmission CQM results in a data file defined by CMS. We expect that this capability would require EHR technology to generate an eXtensible Markup Language (XML) data file with aggregate CQM calculation results in the format CMS would have the capacity to accept. Similar to other CMS quality programs' reporting requirements, we expect that CMS would make available the XML data file template in time for us to adopt it in our final rule. We believe that this approach gives EPs, EHs, and CAHs a default solution for reporting CQMs electronically. We note that if EPs, EHs, and CAHs elect to use their CEHRT to pursue an alternative reporting mechanism permitted by CMS for the EHR Incentive Programs, then it would be the EP, EH, or CAH's responsibility for ensuring compliance with the alternative mechanism's requirements.

• *Auditable events and tamper-resistance; and audit report(s)*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criteria
§ 170.314(d)(2) (Auditable events and tamper-resistance)
§ 170.314(d)(3) (Audit report(s))
Standard
§ 170.210(e) (Record actions related to electronic health information, audit log status, and encryption of end user devices)

The HITSC recommended two revised certification criteria—one focused on the capability to record auditable events and another focused on the capability to create audit reports—in place of the single 2011 Edition EHR certification criterion for audit logs adopted at § 170.302(r). It also recommended, for clarity, that we move the specific capability ''detection'' from the integrity certification criterion (§ 170.302(s)(3)) to the proposed auditable events and tamper-resistance certification criterion. Further, it recommended two versions of this certification criterion. We agree with the HITSC's recommendations because they provide more flexibility and are consistent with the stakeholder feedback we have received since the publication of the S&CC July 2010 final rule. As for the two recommended

[35] *http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_12/20774.*

[36] *https://questions.cms.hhs.gov/app/answers/detail/a_id/10649.*

versions of the certification criterion, we propose a certification criterion that combines both recommended versions.

Stakeholder feedback has indicated that splitting this 2011 Edition certification criterion into two separate certification criteria would permit a wider variety of EHR technologies to be certified as EHR Modules. We have also expanded upon the scope of the HITSC's recommendation to address input from the HHS Office of Inspector General (May 2011 report [37]) and reflect our general belief that a more stringent certification policy for audit logs will ultimately assist EPs, EHs, and CAHs to better detect and investigate breaches. This expansion includes the specific capabilities that the audit log must be enabled by default (i.e., turned on), immutable (i.e., unable to be changed, overwritten, or deleted), and able to record not only which action(s) occurred, but more specifically the electronic health information to which the action applies. The proposed certification criterion would also require that the ability to enable and disable the recording of actions be limited to an identified set of users (e.g., system administrator). Further, to accommodate these changes, we are proposing a revised standard at § 170.210(e) and proposing to require that: (1) When the audit log is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the action(s) that occurred must be recorded; and (2) as applicable, when encryption for end-user devices managed by EHR technology is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the actions that occurred must be recorded.

We did not use the phrase ''security-relevant events'' in the standard, as recommended by the HITSC, because we believe it is ambiguous and provides insufficient guidance in terms of what constitutes an event that would need to be audited. Rather, we believe that the proposed minimum set of actions that would be required to be captured provides greater clarity for EHR technology developers and allows for consistent testing. Finally, we acknowledge, as recommended by the HITSC, that an example implementation specification which could be followed in designing EHR technology to meet these certification criteria could include, but is not limited to ASTM E2147–01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems. We propose to adopt these revised certification criteria at § 170.314(d)(2) and (3); and the revised standard at § 170.210(e).

- *Encryption of data at rest*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion
§ 170.314(d)(7) (Encryption of data at rest)

The HITSC recommended that we revise the ''general encryption'' certification criterion adopted at § 170.302(u) in favor of a certification criterion focused on the capability of EHR technology to encrypt and decrypt electronic health information managed by EHR technology on end-user devices if such electronic health information would remain stored on the devices after use of EHR technology on that device has stopped. Their rationale, with which we agree, was that this approach would be more practical, effective, and easier to implement than the otherwise general encryption requirement adopted at § 170.302(u). Further, we interpret this HITSC recommendation to suggest that we should focus more attention on promoting EHR technology to be designed to secure electronic health information on end-user devices (which are often a contributing factor to a breach of unsecured protected health information [38]). The OIG provided similar rationale in its May 2011 report (cited above) in which it recommended that ONC address IT security controls for encrypting data on mobile devices. Additionally, we understand that the HITSC intended to recommend a certification criterion that would complement already existing HHS policy related to breaches of unsecured protected health information (i.e., the guidance from the HHS Office for Civil Rights on rendering unsecured protected health information unusable, unreadable, or indecipherable to unauthorized individuals [39]). As noted in the guidance provided by the HHS Office for Civil Rights, NIST Special Publication (SP) 800–111 [40] serves as a resource to guide how encryption should be applied to end-user devices.

This proposed certification criterion is drafted to permit EHR technology developers to demonstrate in one of two ways that a Complete EHR or EHR Module is compliant. The first way, § 170.314(d)(7)(i), accounts for circumstances in which EHR technology is designed to manage electronic health information on end-user devices [41] and on which electronic health information would remain stored on the end-user devices after use of the EHR technology on the devices has stopped. We use ''stopped'' to mean that the session has been terminated, including the termination of the network connection. In these circumstances, EHR technology presented for certification must be able to encrypt the electronic health information that remains on end-user devices. And, to comply with paragraph (d)(7)(i), this capability must be enabled (i.e., turned on) by default and only be permitted to be disabled (and re-enabled) by a limited set of identified users. We did not include ''decrypt'' in the proposed certification criterion because we believe that the critical capability to require for certification is the act of encryption after use of the EHR technology on the end-user device has stopped. We presume that EHR technology developers would also include the capability to decrypt the electronic health information, when appropriate; otherwise subsequent use or access to the data would not be possible. We use the phrase ''manages electronic health information'' in this certification criterion to mean that the EHR technology is designed in a way that it can exert control over the electronic health information that remains on an end-user device after the use of EHR technology on that device has stopped. For example, if an EHR technology is designed to manage a client application that can be executed on a laptop or tablet, and electronic health information would remain stored—even in temporary storage—on that end-user device when a user stops using the client application on the laptop or tablet, the EHR technology would need to meet the requirements

[37] *http://oig.hhs.gov/oas/reports/other/180930160.pdf.*

[38] *http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachrept.pdf.*

[39] *http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brguidance.html.*

[40] *http://csrc.nist.gov/publications/nistpubs/800-111/SP800-111.pdf.*

[41] Consistent with NIST SP 800–111, we consider ''end-user devices'' to include, but not be limited to: personal computers, laptops, smart phones, tablet computers, external memory devices and similar removable storage media (e.g., universal serial bus [USB] flash drive, memory card, external hard drive, writeable or re-writeable CD or DVD).

specified at § 170.314(d)(7)(i) in order to be certified.

We recognize that in some scenarios EHR technology may not be designed to manage electronic health information on the end-user devices on which a user may ultimately choose to store electronic health information. For example, an EHR technology may not be designed to manage electronic health information on a USB-drive, but a user may choose to store electronic health information from the EHR technology on such an end-user device. We wish to make clear that in order to comply with this certification criterion, an EHR technology developer would not need to anticipate such scenarios. More specifically, the EHR technology developer would *not* have to demonstrate for certification that the EHR technology could encrypt electronic health information on the USB-drive (or similar end-user device) since the EHR technology was not designed to manage electronic health information on that USB-drive. We further note that if a user chooses to store electronic health information on an end-user device on which EHR technology was not designed to manage electronic health information, then the user would be responsible for ensuring such information is protected in accordance with applicable law.

The second way to demonstrate compliance with this certification criterion would be for an EHR technology developer to demonstrate that its EHR technology can meet § 170.314(d)(7)(ii) and prove that electronic health information managed by EHR technology never remains on end-user devices after use of EHR technology on those devices has stopped. We believe this alternative method is important to include because it: (1) Verifies as part of certification that the EHR technology was, in fact, designed in a way such that it does not enable electronic health information to remain on end-user devices after use of EHR technology on those devices has stopped; (2) Provides EHR technology developers a way to demonstrate compliance with this certification criterion; and (3) It encourages an outcome that is more secure (i.e., when no electronic health information is permitted to remain, the potential for a breach is mitigated). An example of this circumstance would be a situation where an EHR technology is designed to manage a client application on an end-user device (locally or over the Internet) and the client application enables the user to complete a full suite of actions related to electronic health information. Once the use of EHR technology on the end-user device has stopped, the electronic health information does not remain on the device on which the client application was executed.

We propose to adopt this revised certification criterion at § 170.314(d)(7).

- *Immunization registries*

MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

§ 170.314(f)(1) (Immunization information)

§ 170.314(f)(2) (Transmission to immunization registries)

Standards and Implementation Specifications

§ 170.205(e)(3) (HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3); and

§ 170.207(i) (CVX code set: August 15, 2011 version)

The HITSC recommended that we consider splitting this certification criterion into two criteria—one focused on the data capture and the other focused on the formatting of such data in the proposed standards and implementation specifications. We have followed this recommendation and propose two separate certification criteria. We believe this approach could enable additional EHR technologies (likely in the form of EHR Modules) to be certified and provides additional pathways and flexibility to EPs, EHs, and CAHs to have EHR technology that can be used to satisfy the proposed revised definition of CEHRT. We note that we are discussing these criteria together for simplicity and to prevent confusion, but we do not consider the certification criterion we propose to focus on data capture to be a ''revised'' certification criterion. Rather, we believe that the certification criterion proposed at § 170.314(f)(1) constitutes an unchanged certification criterion because all the capabilities included in the criterion are the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(k)).

For the certification criterion proposed at § 170.314(f)(1), consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have replaced the terms ''retrieve'' and ''modify'' in the revised criterion with ''access'' and ''change,'' respectively. For the certification criterion proposed at § 170.314(f)(2), we have stated the ''transmission capability'' as the capability to electronically create immunization information for electronic transmission in accordance with the applicable standards and implementation specifications. We clarify that this criterion focuses on the capability of EHR technology to properly create for transmission immunization information in accordance with the applicable standards and implementation specifications. The criterion does not address the ability to query and evaluate immunization history from the immunizations information systems (IIS) to determine a patient's vaccination need, nor does it address the specific connectivity requirements that an EP, EH, or CAH would need to establish or meet to successfully transmit immunization information, as such requirements are likely to vary from State to State and are outside the scope of certification.

The HITSC recommended, and we agree, that the use of only the HL7 2.5.1 standard should be permitted for submitting immunization information because immunization registries are rapidly moving to this standard. In consultation with the Centers for Disease Control and Prevention, we also propose to adopt the HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.3 as the implementation specification. This release provides corrections and clarifications to Release 1.0 and contains new guidance on how to message vaccines for children (VFC) eligibility. Finally, we propose to adopt the August 15, 2011 version of CVX code sets. We propose to adopt the revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(f)(1) and (2). We propose to adopt the HL7 2.5.1 standard with implementation guide at § 170.205(e)(3) and the CVX code set at § 170.207(i).

- *Public health agencies*

MU Objective

Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

§ 170.314(f)(3) (Public health surveillance)

§ 170.314(f)(4) (Transmission to public health agencies)

Standards and Implementation Specifications

§ 170.205(d)(2) (HL7 2.5.1) and § 170.205(d)(3) (HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1)

Similar to the immunization certification criteria above, the HITSC recommended that we consider splitting the public health surveillance certification criterion into two separate certification criteria. We have followed this recommendation, and we have made similar wording changes to these proposed certification criteria for the same reasons expressed in the revisions to the certification criteria for immunization information and transmission. As noted under the proposed immunization certification criteria, we are discussing these two proposed syndromic surveillance criteria together for simplicity and to prevent confusion, but we do not consider the certification criterion we propose to focus on data capture to be a ''revised'' certification criterion. Rather, we believe that the certification criterion proposed at § 170.314(f)(3) constitutes an unchanged certification criterion because all the capabilities included in the criterion are the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(l)).

The HITSC recommended and we agree that the use of only the HL7 2.5.1 standard should be permitted for formatting syndrome-based public health surveillance information because public health agencies are rapidly moving to this standard and all stakeholders would benefit from focusing on a single public health surveillance standard. The HITSC also recommended and we agree that the standard be constrained for hospitals with the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1. We also believe that certification of ambulatory EHR technology to this guide can be useful for EHR developers that provide EHR technology to eligible professionals that practice in urgent care settings. Therefore, we propose that certification to this guide be optional for the ambulatory setting. We propose to adopt the revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(f)(3) and (4) and the HL7 2.5.1 standard and implementation guide for the inpatient setting (and optional for the ambulatory setting) at § 170.205(d)(3). The required exchange standard for the ambulatory setting has already been adopted at § 170.205(d)(2).

- *Automated measure calculation*

MU Objective *N/A*
2014 Edition EHR Certification Criterion § 170.314(g)(2) (Automated measure calculation)

We propose to adopt a revised automated measure calculation certification criterion for the 2014 Edition EHR certification criteria. We have revised the certification criterion to clearly identify that the recording, calculating, and reporting capabilities required by this certification criterion apply to the numerator and denominator associated with the capabilities that support an MU objective with a percentage-based measure. To be clear, the capabilities to which we refer are the capabilities included in the certification criteria to which the EHR technology is presented for certification.

We want to emphasize that testing to this certification criterion would not only include verification of the ability of EHR technology to generate numerators and denominators, but would also verify the accuracy of the numerators and denominators generated by the EHR technology. We believe that testing to ensure the accuracy of these calculations would significantly reduce the reporting burden for MU attestation. Additionally, testing and certification to this proposed revised certification criterion would include testing and certifying the ability to electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable MU measure that is supported by a capability in the new certification criteria proposed in this rule that are adopted in a final rule.

We propose to adopt this revised certification criterion at § 170.314(g)(2).

b. Ambulatory Setting

We propose to adopt the following revised certification criteria for the ambulatory setting.

- *Electronic prescribing*

MU Objectives Generate and transmit permissible prescriptions electronically (eRx).
2014 Edition EHR Certification Criterion § 170.314(b)(3) (Electronic prescribing) **Standards** § 170.205(b)((2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release)

The HITSC recommended that we adopt a revised certification criterion for the ambulatory setting that required the use of RxNorm as the vocabulary standard. We agree that RxNorm should be adopted as the vocabulary standard instead of the current adopted standard which specifies any source vocabulary that is included in RxNorm. Additionally, with respect to content exchange standards, we are proposing to no longer include the use of NCPDP SCRIPT version 8.1 as a way to meet the 2014 Edition EHR certification criterion because we understand that CMS is planning to propose retiring this standard (adopted as a Medicare Part D e-prescribing standard) in a proposed rule that is scheduled to be issued soon after this proposed rule is published. If we should receive information indicating a change in CMS' plans prior to the issuance of our final rule, we may, based also on public comment, reinstate this standard in a final revised certification criterion. We believe that it is appropriate for this certification criterion to be adopted for both the ambulatory and inpatient settings (as discussed under the proposed new certification criteria section) as it supports our desired policy and interoperability outcome for content exchange standards to be used when information is exchanged between different legal entities. We propose to adopt this revised certification criterion at § 170.314(b)(3) and the February 6, 2012 Release of the RxNorm standard at § 170.207(h).

- *Clinical summaries*

MU Objective Provide clinical summaries for patients for each office visit.
2014 Edition EHR Certification Criterion § 170.314(e)(2) (Ambulatory setting only—clinical summaries) **Standards** § 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639–1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED–CT® International Release January 2012); § 170.207(m) (ICD–10–CM); § 170.207(b)(2) (HCPCS and CPT–4) or § 170.207(b)(3) (ICD–10–PCS); § 170.207(g) (LOINC version 2.38); and § 170.207(h) (RxNorm February 6, 2012 Release)

The HITSC recommended that the certification criterion be revised for the 2014 Edition EHR certification criteria to reflect the proposed new and revised standards for problem lists and other vocabulary standards. We agree with these recommendations. We have made several refinements to the recommended revised certification criterion to ensure that EHR technology meets the appropriate standards and is capable of making available the information CMS

is proposing be provided to a patient after an office visit.

We further propose that when information is provided electronically, the information be provided according to the Consolidated CDA standard. For the same reasons as provided in the new ''view, download, and transmit to 3rd party'' certification criterion discussion, we believe that adopting the Consolidated CDA for this certification criterion is advantageous since its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS is proposing be provided to a patient after an office visit. As we similarly noted in the discussion of the transitions of care certification criteria (§ 170.314(b)(1) and (2)), we considered, but have not proposed, adopting separate certification criteria to explicitly require the capture of unique data elements included in clinical summaries, such as care plans and future scheduled tests. We welcome public comment on whether we should adopt separate certification criteria for these data elements. For certain other data elements in § 170.314(e)(2), we propose to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard. These vocabulary standards have been previously adopted or are proposed for adoption in this proposed rule, consistent with the recommendations of the HITSC. We propose to adopt this revised certification criterion for the 2014 Edition EHR certification criteria at § 170.314(e)(2).

c. Inpatient Setting

We propose to adopt the following revised certification criteria for the inpatient setting.

• *Reportable laboratory tests and values/results*

MU Objective

Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

§ 170.314(f)(5) (Inpatient setting only—reportable laboratory tests and values/results)

§ 170.314(f)(6) (Inpatient setting only—transmission of reportable laboratory tests and values/results)

Standards and Implementation Specifications

§ 170.205(g) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38)

Similar to the immunization and syndromic surveillance certification criteria above, the HITSC recommended that we consider splitting the ''reportable laboratory results'' certification criterion into two separate certification criteria. We have followed this recommendation, and for the same reasons expressed above, we have made similar wording changes to these proposed certification criteria. Also, as noted under the proposed immunization and syndromic surveillance certification criteria, we are discussing these two proposed laboratory tests and values/results certification criteria together for simplicity and to prevent confusion, but we do not consider the certification criterion we propose to focus on data capture to be a revised certification criterion. Rather, we believe that the certification criterion proposed at § 170.314(f)(5) constitutes an unchanged certification criterion because all the capabilities included in the criterion are the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.306(g)).

The HITSC recommended that we maintain the use of only the HL7 2.5.1 standard and that we adopt the most current version of LOINC as the vocabulary standard. We agree and propose to adopt LOINC version 2.38 as the vocabulary standard as it is the most recent version. Based on our consultation with the Centers for Disease Control and Prevention, we also propose to adopt HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata and SNOMED CT® International Release January 2012 version. This version of the implementation guide contains corrections and will require minor changes to conformance testing and certification to account for newly assigned OIDs (object identifiers) identifying the message profiles in the implementation guide. The International Release January 2012 version of SNOMED CT® is the most recent version and SNOMED CT® is required by the implementation guide, as is LOINC. We propose to adopt the revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(f)(5) and (6). We propose to adopt the HL7 2.5.1 standard with the revised implementation guide at § 170.205(g). We propose to adopt the version of SNOMED CT® at § 170.207(a)(3) and LOINC version 2.38 standard at § 170.207(g).

6. Unchanged Certification Criteria

In our prior rulemakings, we did not expressly describe what we considered to be ''unchanged'' certification criteria. Based on our experience with this rulemaking, we take this opportunity to describe the certification criteria that we would consider unchanged. We would consider the following factors in determining whether a certification criterion is unchanged:

• The certification criterion includes only the same capabilities that were specified in previously adopted certification criteria;

• The certification criterion's capabilities apply to the same setting as they did in previously adopted certification criteria; and

• The certification criterion remains designated as ''mandatory,'' or it is re-designated as ''optional,'' for the same setting for which it was previously adopted certification criterion.

For clarity, we explain that an unchanged certification criterion could be a certification criterion that includes capabilities that were merged from multiple previously adopted certification criteria as long as the capabilities specified by the merged certification criterion remain the same. The ''authentication, access control, and authorization'' certification criterion discussed below and proposed for adoption at § 170.314(d)(1) meets this description. Additionally, an unchanged certification criterion could be a certification criterion that has fewer capabilities than a previously adopted certification criterion as long as the capabilities that remain stay the same. The ''integrity'' certification criterion discussed below and proposed for adoption at § 170.314(d)(8) meets this description. As discussed in the description of revised certification criteria, a certification criterion could be characterized differently based on the setting to which it applies or the designation it is given (''mandatory'' or ''optional''). For example, a certification criterion that includes the same capabilities that were specified in a previously adopted certification criterion would be considered unchanged for the ambulatory setting if the previously adopted certification criterion only applied to the ambulatory setting and certification to the criterion was ''mandatory.'' However, this same certification criterion would be considered new for the inpatient setting

if it were subsequently adopted for both settings.

We identify some of the proposed unchanged certification criteria included in the 2014 Edition EHR certification criteria below and have also identified unchanged certification criteria previously in the preamble. As noted, the capabilities included in the certification criteria below are the same capabilities that were adopted in 2011 Edition EHR certification criteria. We propose to add all of these unchanged certification criteria to the 2014 Edition EHR certification criteria at § 170.314.

a. Refinements to Unchanged Certification Criteria

We propose to refine the following certification criteria as discussed below.

- *Computerized provider order entry*

MU Objective
Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.
2014 Edition EHR Certification Criterion
§ 170.314(a)(1) (Computerized provider order entry)

We have merged the separate ambulatory and inpatient CPOE certification criteria in the 2011 Edition EHR certification criteria into one criterion because they are identical. Consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have also replaced the terms ''modify'' and ''retrieve'' with ''change'' and ''access,'' respectively. We have also removed the term ''store'' from the criterion because it is redundant with our interpretation of the term ''record.'' Finally, we moved the phrase ''at a minimum'' in the sentence to eliminate any possible ambiguity as to what the phrase modifies. As the proposed certification criterion is now written, we believe it is clear that the phrase modifies the order types and not the terms ''record,'' ''change,'' and ''access.''

- *Vital signs, body mass index, and growth charts*

MU Objective
Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0–20 years, including BMI.

2014 Edition EHR Certification Criterion
§ 170.314(a)(4) (Vital signs, body mass index, and growth charts)

Consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have replaced the terms ''modify'' and ''retrieve'' with ''change'' and ''access,'' respectively. We have also added the alternative term ''length'' to go with ''height'' as it is the clinically appropriate term for newborns and clarified the intent of the ''vital signs'' capability. The only other refinements that we propose are for the plot and display growth charts capability. First, we propose that this capability be designated ''optional'' within this certification criterion because even though this certification criterion is proposed to be part of a Base EHR that every EP, EH, and CAH would need to have in order to satisfy the proposed revised definition of CEHRT, some EPs, EHs, and CAHs would not (or would never) use such a capability due to scope of practice or other reasons. Thus, to reduce regulatory burden and to not require EHR technology developers to include a specific growth chart capability when they do not intend to market their EHR technology to EPs, EHs, or CAHs that would use such a capability, we have designated it as ''optional'' for certification. In addition, we propose to remove the age range reference (2–20 years old) from this capability. This is consistent with other certification criteria such as ''smoking status'' where the MU objective it supports specifies an age threshold (13), but the capability is not dependent on the patient's age.

- *Smoking status*

MU Objective
Record smoking status for patients 13 years old or older.

2014 Edition EHR Certification Criterion
§ 170.314(a)(11) (Smoking status)
Standard
§ 170.207(l) (smoking status types)

As part of the 2011 Edition EHR certification criteria, the smoking status certification criterion is codified at § 170.302(g), specifying a list of six smoking status types that EHR technology must be capable of recording, modifying, and retrieving. Consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have replaced the terms ''modify'' and ''retrieve'' with ''change'' and ''access,'' respectively. We also propose to specify the six smoking status types included in the 2011 Edition EHR certification criterion as a standard at § 170.207(l). This refinement will provide additional clarity for the certification criterion and consistency with the structure of similar certification criteria.

- *Patient reminders*

MU Objective
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

2014 Edition EHR Certification Criterion
§ 170.314(a)(15) (Ambulatory setting only—patient reminders)

We clarify and emphasize that EHR technology certified to this certification criterion would need to be capable of creating a patient reminder list that includes a patient's communication preferences, which would be consistent with current testing procedures for this capability as included in the 2011 Edition EHR certification criterion (§ 170.304(d)). We also note that, consistent with patient communication preferences, we would anticipate that EPs, EHs, and CAHs could use communication mediums made available by EHR technology certified to the proposed ''secure messaging'' certification criterion (§ 170.314(e)(3)) or the ''view, download and transmit to 3rd party'' certification criterion (§ 170.314(e)(1)) to send patient reminders. We also anticipate that other modes of communication would be available and may be preferred by patients for sending patient reminders, such as regular mail.

- *Authentication, access control, and authorization*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2014 Edition EHR Certification Criterion
§ 170.314(d)(1) (Authentication, access control, and authorization)

As part of the 2011 Edition EHR certification criteria, the ''access control'' certification criterion is codified at § 170.302(o) and the ''authentication'' certification criterion is codified at § 170.302(t). Based on consultations with NIST, the similarity of the two test procedures that were developed for these certification criteria, and that these capabilities go hand-in-hand, we have determined that it would be best to merge the two certification criteria. We believe this would allow for more efficient testing and is consistent with EHR technology development.

Given this proposal, we have adopted in part the recommendations of the HITSC, which are reflected in the proposed certification criterion. We have also expressed the HITSC's authentication recommendation as additional guidance for this certification criterion in that the capability to authenticate human users would consist of the assertion of an identity and presentation of at least one proof of that identity. We intend and believe that it is most appropriate for this certification criterion to focus on users that would be able to access electronic health information in EHR technology at a EP, EH, or CAH and not to focus on external users that may make requests for access to health information contained in the EHR technology for the purpose of electronic health information exchange. The latter purpose would likely require a different/additional security approach(es) and rely on a health care provider's overall infrastructure beyond its EHR technology. We also acknowledge, as recommended by the HITSC, that example standards and implementation specifications which could be followed in designing EHR technology to meet this certification criterion could include, but are not limited to: NIST Special Publication 800–63, Level 2 (single-factor authentication) and ASTM, E1986–09 (Information Access Privileges to Health Information).

- *Automatic log-off*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2014 Edition EHR Certification Criterion
§ 170.314(d)(5) (Automatic log-off)

We are not revising or refining this certification criterion as part of the proposed 2014 Edition EHR certification criteria, but are clarifying that to terminate a session should not be confused with locking a session, where access to an active session is permitted after re-authentication. EHR technology must have the capability to terminate the session, including terminating the network connection.

- *Emergency access*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2014 Edition EHR Certification Criterion
§ 170.314(d)(6) (Emergency access)

We are refining the 2011 Edition EHR certification criterion for emergency access codified at § 170.302(p) for the 2014 Edition EHR certification criteria by removing the parenthetical ''who are authorized for emergency situations'' from the certification criterion and including the phrase ''identified set of users'' to more clearly convey this certification criterion's intent and to consistently use this phrase through every certification criterion where we intend for the same capability to be available. The purpose of this criterion is to provide certain users (''identified set of users'') with the ability to override normal access controls in the case of an emergency. The refinement to the criterion coupled with our explanation should provide sufficient clarity for testing and certifying to this certification criterion.

- *Integrity*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2014 Edition EHR Certification Criterion
§ 170.314(d)(8) (Integrity)

Standard
§ 170.210(c) (Verification that electronic health information has not been altered)

The certification criterion at § 170.314(d)(8) is consistent with the recommendation and recommended certification criterion by the HITSC for the 2014 Edition EHR certification criteria. The capability to detect changes to an audit log has been removed from this proposed certification criterion and added to the proposed certification criterion for ''auditable events and tamper resistance'' at § 170.314(d)(2). The adopted certification criterion at § 170.304(b) specifies that EHR technology must be able to create a message digest in accordance with the standard specified at § 170.210(c). The adopted standard is: ''A hashing algorithm with a security strength equal to or greater than SHA–1 (Secure Hash Algorithm (SHA–1)) * * * must be used to verify that electronic health information has not been altered.'' After consultation with NIST, we understand that the strength of a hash function in digital signature applications is limited by the length of the message digest and that in a growing number of circumstances the message digest for SHA–1 is too short for secure digital signatures (SHA–2 produces a 256-bit message digest that is expected to remain secure for a long period of time). We also understand that certain operating systems and applications upon which EHR technology may rely use SHA–1 and do not or cannot support SHA–2 at the present time. Thus, we request public comment on whether we should leave the standard as it currently reads or replace SHA–1 with SHA–2.

b. Unchanged Certification Criteria Without Refinements

The following table (Table 2) identifies the proposed unchanged 2014 Edition EHR certification criteria and the corresponding 2011 Edition EHR certification criteria that include the same capabilities that are in the proposed unchanged 2014 Edition EHR certification criteria. We propose to adopt these certification criteria as part of the 2014 Edition EHR certification criteria without any substantial refinements, except, consistent with our discussion in the preamble section titled ''Explanation and Revision of Terms Used in Certification Criteria,'' we have, where appropriate, replaced the terms ''generate,'' ''modify,'' and ''retrieve'' with ''create,'' ''change,'' and ''access,'' respectively. Table 2 also identifies the corresponding paragraphs of § 170.314 where the certification criteria would be added and the proposed titles of those paragraphs/certification criteria.

TABLE 2—UNCHANGED CERTIFICATION CRITERIA WITHOUT REFINEMENTS

2014 Edition		2011 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
170.314(a)(10)	Drug-formulary checks	170.302(b)	Drug-formulary checks.
170.314(a)(6)	Medication list	170.302(d)	Maintain active medication list.
170.314(a)(7)	Medication allergy list	170.302(e)	Maintain active medication allergy list.
170.314(a)(14)	Patient lists	170.302(i)	Generate patient lists.
170.314(d)(9)	Accounting of disclosures	170.302(w)	Accounting of disclosures.

TABLE 2—UNCHANGED CERTIFICATION CRITERIA WITHOUT REFINEMENTS—Continued

2014 Edition		2011 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
170.314(a)(18)	Advance directives	170.306(h)	Advance directives.

7. Gap Certification

In the Permanent Certification Program final rule (76 FR 1307), we explained the concept of ''gap certification'' and defined it at § 170.502 as ''the certification of a previously certified Complete EHR or EHR Module(s) to: (1) [a]ll applicable new and/or revised certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results of a NVLAP-accredited testing laboratory; and (2) [a]ll other applicable certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results used to previously certify the Complete EHR or EHR Module(s).'' We stated that gap certification will focus on the difference between certification criteria that are adopted through rulemaking at different points in time. We discussed in section III.A of this preamble the factors we would consider in determining whether a proposed 2014 Edition EHR certification criterion is ''new'' or ''revised.'' Examples of new certification criteria are the ''secure messaging'' certification criterion we propose for adoption at § 170.314(e)(3) and the ''electronic medication administration record'' certification criterion we propose for adoption at § 170.314(a)(17). An example of a revised certification criterion is the ''CDS'' certification criterion we propose for adoption at § 170.314(a)(8). This certification criterion is ''revised'' because it would add capabilities to the certification criteria for CDS that were previously adopted at §§ 170.304(e) and 170.306(c). An example of a certification criterion that we would consider both new and revised is the ''e-prescribing'' certification criterion proposed for adoption at § 170.314(b)(3). This certification criterion is a revised certification criterion for the ambulatory setting, but would be considered a new certification criterion for the inpatient setting.

For a Complete EHR or EHR Module that was previously certified to the 2011 Edition EHR certification criteria to be certified to the 2014 Edition EHR certification criteria, test results from a NVLAP-accredited testing laboratory would be required for all of the applicable new and revised certification criteria that are adopted. However, for the certification criteria that we identify as unchanged, test results that were used previously to certify a Complete EHR or EHR Module to the 2011 Edition EHR certification criteria identified in Table 3 below could be used to certify the Complete EHR or EHR Module to the corresponding 2014 Edition EHR certification criteria identified in the table. To illustrate, for gap certification, an EHR Module that was previously certified to the ''CPOE'' and ''drug-drug, drug-allergy interaction checks'' certification criteria (i.e., previously tested and certified to § 170.304(a) or § 170.306(a) and § 170.302(a)) would not need to be retested to the ''CPOE'' certification criterion we propose to add to the 2014 Edition EHR certification criteria at § 170.314(a)(1) because this criterion has been identified as an unchanged certification criterion. However, the previously certified EHR Module *would need* to be retested for ''drug-drug, drug-allergy interaction checks'' because we have proposed to adopt a revised certification criterion for ''drug-drug, drug-allergy interaction checks'' as part of the 2014 Edition of EHR certification criteria at § 170.314(a)(2). We note, as identified in Table 3, that for the proposed certification criterion at § 170.314(b)(5) (Incorporate laboratory tests and values/results), EHR technology designed for an ambulatory setting would need to be tested by a NVLAP-accredited testing laboratory because we propose to require that such EHR technology meet new standards and implementation specifications, while the capabilities required for the inpatient setting are unchanged.

TABLE 3—GAP CERTIFICATION: CROSSWALK OF UNCHANGED 2014 EDITION EHR CERTIFICATION CRITERIA TO THE CORRESPONDING 2011 EDITION EHR CERTIFICATION CRITERIA

2014 Edition		2011 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
170.314(a)(10)	Drug-formulary checks	170.302(b)	Drug-formulary checks.
170.314(a)(6)	Medication list	170.302(d)	Maintain active medication list.
170.314(a)(7)	Medication allergy list	170.302(e)	Maintain active medication allergy list.
170.314(a)(4)	Vital signs, body mass index, and growth charts.	170.302(f)	Vital signs.
170.314(a)(11)	Smoking status	170.302(g)	Smoking status.
170.314(b)(5)	Incorporate laboratory tests and values/results (inpatient setting only)	170.302(h)	Incorporate laboratory test results.
170.314(a)(14)	Patient lists	170.302(i)	Generate patient lists.
170.314(f)(1)	Immunization information	170.302(k)	Submission to immunization registries.
170.314(f)(3)	Public health surveillance	170.302(l)	Public health surveillance.
170.314(d)(1)	Authentication, access control, and authorization.	170.302(o)	Access control.
170.314(d)(6)	Emergency access	170.302(p)	Emergency access.
170.314(d)(5)	Automatic log-off	170.302(q)	Automatic log-off.
170.314(d)(8)	Integrity	170.302(s)	Integrity.
170.314(d)(1)	Authentication, access control, and authorization.	170.302(t)	Authentication.
170.314(d)(9)	Accounting of disclosures	170.302(w)	Accounting of disclosures.
170.314(a)(15)	Patient reminders	170.304(d)	Patient reminders.

TABLE 3—GAP CERTIFICATION: CROSSWALK OF UNCHANGED 2014 EDITION EHR CERTIFICATION CRITERIA TO THE CORRESPONDING 2011 EDITION EHR CERTIFICATION CRITERIA—Continued

2014 Edition		2011 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
170.314(a)(1)	CPOE	170. 304(a) 170. 306(a)	CPOE.
170.314(f)(5)	Reportable laboratory tests and values/results	170.306(g)	Reportable lab results.
170.314(a)(18)	Advance directives	170.306(h)	Advance directives.

As we have previously stated in our rules (75 FR 11351, 76 FR 1308), we believe gap certification is a less costly and more efficient certification option for EHR technology developers to get their EHR technologies certified without the time and costs associated with retesting to unchanged certification criteria. As we established in the permanent certification program final rule (76 FR 1308), however, gap certification will only be available under the permanent certification program, which we are proposing to rename the ''ONC HIT Certification Program.'' We have extended the sunset date of the temporary certification program (and delayed the start of the ONC HIT Certification Program), which was originally anticipated to be December 31, 2011. The sunset date will now coincide with the effective date of the final rule that will result from this proposed rule (76 FR 68192).

B. Redefining Certified EHR Technology and Related Terms

1. Proposed Revisions to the Definition of Certified EHR Technology

Certified EHR Technology is defined in section 3000(1) of the PHSA as a ''qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).'' In the S&CC July 2010 final rule (75 FR 44590), we further defined Certified EHR Technology (CEHRT) at § 170.102 in relation to the applicable setting-specific certification criteria (ambulatory or inpatient) adopted by the Secretary to mean:

1. A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or

2. A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Under the current definition, EPs, EHs, and CAHs must have Certified EHR Technology that has been tested and certified to all applicable certification criteria adopted for the setting (ambulatory or inpatient) for which it was designed. We refer readers to frequently asked question (FAQ) 9–10–017–2 for further explanation.[42] Since the publication of the S&CC July 2010 Final Rule, ONC and CMS have received feedback on the definition of CEHRT from numerous stakeholders, including EPs, EHs, CAHs, EHR technology developers, and multiple associations representing these and other stakeholders. Overall, a majority of stakeholders felt that we should change our CEHRT policy to provide EPs, EHs, and CAHs the flexibility to have or possess only the CEHRT they will use to demonstrate MU. This view was supported by the HITSC in their November 16, 2011 recommendation (transmitted to ONC on January 17, 2012) that we consider requiring EPs, EHs, and CAHs to possess EHR technology that has been certified only to the certification criteria that include capabilities they will use to attempt to achieve MU. Such a change would mean that the definition of CEHRT would be largely determined or driven by how an EP, EH, or CAH chooses to accomplish MU rather than requiring certification to all certification criteria adopted for an applicable setting (ambulatory or inpatient).

We have considered all of the feedback we have received, particularly the recommendation of the HITSC, and are proposing a revised definition of CEHRT that would provide significantly more flexibility for EPs, EHs, and CAHs than exists under the current definition. We are convinced by stakeholder feedback and our own independent fact-finding that when combined with the complexity of the health care delivery environment, the current CEHRT definition has, in some cases, introduced challenges for certain EPs, EHs, and CAHs by requiring them to have EHR technology they would not necessarily choose to use to demonstrate MU under the EHR Incentive Programs. For example, under CMS regulations, an EP who has no office visits during the EHR reporting period may qualify for an exclusion for the MU objective and associated measure requiring clinical summaries to be provided to patients for each office visit, but under our current definition of CEHRT, the EP must still have EHR technology that supports this capability. Accordingly, consistent with the instruction of the President's Executive Order (EO) 13563 to identify and consider regulatory approaches that reduce burden and maintain flexibility for the public, we have decided to propose a revised definition of CEHRT that we believe would more closely align with the desired flexibility stakeholders have requested while reducing the potential burden associated with acquiring EHR technology. We propose to revise the definition of CEHRT at § 170.102 to read:

Certified EHR technology means:

1. For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:

i. A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or

ii. A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and

[42] *http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3163&PageID=20779.*

certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

2. For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:

i. The capabilities required to meet the definition of a Base EHR; and

ii. All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

As noted in the ''Executive Summary'' (section I.A) of this preamble, FY applies to EHs and CAHs and CY applies to EPs. For the first part of the revised definition of CEHRT that would apply for the FYs/CYs up to and including 2013, we note two specific changes. The first is to include a reference to ''the 2011 Edition EHR certification criteria'' in order to make clear that these are the certification criteria previously adopted by the Secretary at §§ 170.302, 170.304, and 170.306. This clarification is necessary because if the proposed 2014 Edition EHR certification criteria are subsequently adopted in a final rule at § 170.314, there would be two ''editions'' of adopted certification criteria in the CFR. Both the 2011 Edition and the 2014 Edition EHR certification criteria must be effective at the same time for EHR technology to continue to be tested and certified to the 2011 Edition EHR certification criteria and so EHR technology developers may begin to have their EHR technology tested and certified to the 2014 Edition EHR certification criteria.

The second change would allow EPs, EHs, and CAHs to satisfy the definition by having EHR technology certified to the 2014 Edition EHR certification criteria that are ''equivalent'' to the 2011 Edition EHR certification criteria. We would consider ''equivalent'' certification criteria to be those proposed 2014 Edition EHR certification criteria that include capabilities that are at least equal to the capabilities included in certification criteria that were previously adopted as part of the 2011 Edition EHR certification criteria. For a cross-walk between 2011 Edition EHR certification criteria and what we would consider equivalent proposed 2014 Edition EHR certification criteria, see Table 4 below. We believe this revision is necessary and that our proposal provides EPs, EHs, and CAHs with the flexibility to adopt or upgrade to EHR technology certified to the 2014 Edition EHR certification criteria without adversely affecting the certified status of previously adopted EHR technology or their ability to meet the definition of CEHRT. We note, however, that with respect to CQMs, EPs, EHs, and CAHs who adopt or upgrade to EHR technology certified to the 2014 Edition EHR certification criteria during FY/CY 2012 or FY/CY 2013 must ensure that their CEHRT will enable them to report on the CQMs required for the 2012 and 2013 EHR reporting periods. More specifically, the EHR technology required to electronically capture, calculate, and report CQMs during those years will be different than the EHR technology needed to do the same in FY/CY 2014 and subsequent years because CMS has not proposed to change the set of CQMs on which EPs, EHs, and CAHs would need to report until FY/CY 2014. Therefore, EPs, EHs, and CAHs will need to have EHR technology certified to the CQM certification criteria included in the 2011 Edition EHR certification criteria to be able to report on the CQMs required for the 2012 and 2013 EHR reporting periods. For further guidance, we encourage EPs, EHs, and CAHs to read CMS' Stage 2 proposed rule to understand the CQMs that would need to be reported for a given EHR reporting period.

Table 4. Equivalent Certification Criteria				
2011 Edition		2014 Edition		2014 Edition
Ambulatory	Inpatient	Ambulatory	Inpatient	Certification Criterion Name
§ 170.304(a)	§ 170.306(a)	§ 170.314(a)(1)		Computerized provider order entry
§ 170.302(a)		§ 170.314(a)(2)		Drug-drug, drug-allergy interaction checks
§ 170.304(c)	§ 170.306(b)	§ 170.314(a)(3)		Demographics
§ 170.302(f)		§ 170.314(a)(4)		Vital signs, body mass index, and growt charts
§ 170.302(c)		§ 170.314(a)(5)		Problem list
§ 170.302(d)		§ 170.314(a)(6)		Medication list
§ 170.302(e)		§ 170.314(a)(7)		Medication allergy list
§ 170.304(e)	§ 170.306(c)	§ 170.314(a)(8)		Clinical decision support
§ 170.302(b)		§ 170.314(a)(10)		Drug-formulary checks
§ 170.302(g)		§ 170.314(a)(11)		Smoking status
§ 170.302(i)		§ 170.314(a)(14)		Patient lists
§ 170.304(d)		§ 170.314(a)(15)		Patient reminders
§ 170.302(m)		§ 170.314(a)(16)		Patient-specific education resources
	§ 170.306(h)		§ 170.314(a)(18)	Advance directives
§ 170.304(i)	§ 170.306(f)	§ 170.314(b)(1)/ § 170.314(b)(2)		Transitions of care – incorporate/create & transmit summary care record
§ 170.304(b)		§ 170.314(b)(3)		Electronic prescribing
§ 170.302(j)		§ 170.314(b)(4)		Clinical information reconciliation
§ 170.302(h)		§ 170.314(b)(5)		Incorporate lab tests and values/results
§ 170.302(o)		§ 170.314(d)(1)		Authentication, access control, and authorization
§ 170.302(t)		§ 170.314(d)(1)		Authentication, access control and authorization
§ 170.302(r)		§ 170.314(d)(3)		Audit report(s)
§ 170.302(q)		§ 170.314(d)(5)		Automatic log-off
§ 170.302(p)		§ 170.314(d)(6)		Emergency access
§ 170.302(u)		§ 170.314(d)(7)		Encryption of data at rest
§ 170.302(s)		§ 170.314(d)(8)		Integrity
§ 170.302(w)		§ 170.314(d)(9)		Accounting of disclosures (optional)
§ 170.304(g)		§ 170.314(e)(1)		View, download, and transmit to 3rd party
§ 170.304(f)	§ 170.306(d)	§ 170.314(e)(1)		View, download, and transmit to 3rd party
	§ 170.306(e)	§ 170.314(e)(1)		View, download, and transmit to 3rd party
§ 170.304(h)		§ 170.314(e)(2)		Clinical Summaries
§ 170.302(k)		§ 170.314(f)(1)/ § 170.314(f)(2)		Immunization information/Transmission to immunization registries
§ 170.302(l)		§ 170.314(f)(3)/ § 170.314(f)(4)		Public health surveillance/ Transmission to PH agencies
	§ 170.306(g)		§170.314(f)(5)/ §170.314(f)(6)	Reportable lab tests and values/results & Transmission of reportable lab tests and values/results
§ 170.302(n)		§ 170.314(g)(2)		Automated measure calculation

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The second part of the revised definition of CEHRT that would apply beginning with FY/CY 2014 would accomplish four main policy goals:

1. It defines CEHRT in plain language and makes the definition and its requirements readily understandable to EPs, EHs, CAHs, EHR technology developers, and other stakeholders.

2. It continues the progress towards increased interoperability requirements

for EHR technology by requiring all CEHRT to have, at a minimum, the capabilities of a Base EHR.

3. It accounts for stakeholder feedback, which expressed that the definition should align more closely with MU requirements under the EHR Incentive Programs.

4. It follows the tenets expressed in EO 13563 by reducing regulatory burden, providing more flexibility to the regulated community, and making regulatory text more understandable.

We believe it is important to briefly remind stakeholders that the definition of CEHRT does not speak to just one audience. EPs, EHs, and CAHs may view the definition of CEHRT in a way that informs them of the EHR technology that they must possess to accomplish MU. Alternatively, EHR technology developers may see the definition differently and in a way that informs them of the potential market demand for certain EHR technologies and, more specifically, the EHR technology that their customers will need to achieve MU.

Two types of EHR technology, Complete EHRs and EHR Modules, can be certified under the ''ONC HIT Certification Program,'' which is the new name we are proposing for the permanent certification program (see section IV.A below). Under the revised definition of CEHRT that we are proposing for FY/CY 2014 and subsequent years, an EP, EH, or CAH could meet the definition with a certified Complete EHR, a single certified EHR Module, a combination of separately certified EHR Modules, or any combination of the three. For example, an EHR technology developer could get an EHR Module certified that would subsequently enable an EP, EH, or CAH to have EHR technology that would satisfy the proposed revised definition of CEHRT. Alternatively, an EP, EH, or CAH could use a certified Complete EHR and a certified EHR Module to meet the proposed revised definition of CEHRT.

Consistent with stakeholder feedback, an EP, EH, or CAH would generally *not need* to have or possess EHR technology in the following two scenarios in order to satisfy the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years. One scenario would be where an EP, EH, or CAH qualifies for an exclusion for a MU objective and associated measure. With respect to this scenario, we expect that this new flexibility would apply in situations where the MU objective and associated measure would not be applicable to the EP, EH, or CAH. In most cases, we expect this would occur for EPs based on their scope of practice and would be significantly less likely to occur for most EHs and CAHs. For example, a dentist will never give immunizations and, thus, would not need EHR technology with the capability to submit immunization information to immunization registries in order to satisfy the proposed revised definition of CEHRT. As another example, and as noted earlier, an EP may not have any office visits during an EHR reporting period and thus may qualify for the exclusion for the MU objective and associated measure requiring clinical summaries to be provided to patients for each office visit. Under the proposed revised definition of CEHRT, the EP would not need to have EHR technology that supports this capability. The second scenario would be where an EP, EH, or CAH is able to and has chosen to defer a MU ''menu set'' objective and associated measure for a particular stage of MU. In such a case, the EP, EH, or CAH would not necessarily need to have EHR technology with the capability to meet the menu set objective and associated measure in order to have EHR technology that satisfies the proposed revised definition of CEHRT. Ultimately, under the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years, the EP, EH, and CAH will be responsible for ensuring that they have the necessary EHR technology to meet the definition of a Base EHR and support the MU objectives and measures that they seek to achieve under the EHR Incentive Programs. This means that EPs, EHs, and CAHs could run the risk of not having sufficient CEHRT to support their achievement of MU if, for example, they turn out not to be able to exclude a MU objective and measure as anticipated or they end up needing to satisfy a menu objective and measure that they originally expected to defer.

We emphasize that under the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years, all EPs, EHs, and CAHs *must have* EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that meets the definition of a Base EHR as defined below. For example, even if an EP could claim an exclusion from the MU objective and associated measure for CPOE, he or she would still need to have EHR technology that has been certified to the CPOE certification criterion adopted by the Secretary because this capability would be included in a Base EHR.

We have consulted with CMS and have determined that it would be least confusing and burdensome for EPs, EHs, CAHs, and EHR technology developers if this revised definition would apply beginning with the EHR reporting periods that will occur in FY/CY 2014. This approach would account for the proposed start of MU Stage 2 in FY/CY 2014; the policy change we have made related to the definition of a Base EHR; the time it would take EHR developers to update their EHR technology to meet the proposed new and revised certification criteria and have the EHR technology tested and certified to those criteria; and the time it would take EPs, EHs, and CAHs to subsequently implement EHR technology certified to the 2014 Edition EHR certification criteria. We request public comment on alternative approaches we should consider that would provide equivalent simplicity and flexibility for EPs, EHs, and CAHs, as well as EHR technology developers, but that would still meet our programmatic goals and timelines.

The revised definition of CEHRT would apply for all EPs, EHs, and CAHs, regardless of whether they are in Stage 1 or Stage 2 of MU. For example, EPs, EHs, and CAHs that are in Stage 1 or Stage 2 of MU for the EHR reporting periods in FY/CY 2014 would need to meet the revised definition of CEHRT (which includes the definition of a Base EHR). Table 5 is intended to provide a general overview of the proposed revised definition of CEHRT in relation to the stages of MU and the EHR reporting periods in FY/CY 2011 through 2014 (including the extension of Stage 1 in 2013 as proposed by CMS).

TABLE 5—PROPOSED REVISED DEFINITION OF CEHRT

EHR reporting periods			
FY/CY 2011	FY/CY 2012	FY/CY 2013	FY/CY2014
MU Stage 1	MU Stage 1	MU Stage 1	MU Stage 1 *or* MU Stage 2
All EPs, EHs, and CAHs must have EHR technology that has been certified to all applicable 2011 Edition EHR certification criteria or equivalent 2014 Edition EHR certification criteria adopted by the Secretary.			All EPs, EHs, and CAHs must have EHR technology (including a Base EHR) that has been certified to the 2014 Edition EHR certification criteria that would support the objectives and measures, and their ability to successfully report the CQMs, for the MU stage that they seek to achieve.

2. Base EHR

Section 3000(1) of the PSHA defines Certified EHR Technology to include a Qualified EHR. Section 3000(13), in turn, defines a ''qualified electronic health record'' or Qualified EHR as an electronic record of health-related information on an individual that:

1. Includes patient demographic and clinical health information, such as medical history and problem lists; and

2. Has the capacity:

i. To provide clinical decision support;

ii. To support physician order entry;

iii. To capture and query information relevant to health care quality; and

iv. To exchange electronic health information with, and integrate such information from other sources.

This definition of Qualified EHR is codified at 45 CFR 170.102 and is part of the current definition of CEHRT. We now propose to add the term ''Base EHR'' to § 170.102. This term is essentially a substitution for the term ''Qualified EHR'' in the revised definition of CEHRT that would apply in FY/CY 2014 and subsequent years. A Base EHR would have all of the capabilities specified in the statutory definition of a Qualified EHR (that is, in section 3000(13) of the PHSA) and additional capabilities as described below. Hereafter, we intend to use the term ''Qualified EHR'' only as necessary and to refer to the statutory definition, unless otherwise indicated. We believe that the term ''Base EHR'' is more intuitive and conveys a plain language meaning. Moreover, the term ''Qualified EHR'' does not inherently convey the kinds of capabilities it includes. The term ''Base EHR,'' though, conveys that the EHR technology possesses capabilities that are fundamental and should be a *part of* any CEHRT that an EP, EH, or CAH must have to demonstrate MU. We also note that the terms ''qualified EHR'' and ''qualified EHR products'' have been used by CMS in other programs and with a different meaning. Therefore, we believe that the term ''Base EHR'' will be more easily understood and readily accepted by stakeholders.

We propose to define a Base EHR as an electronic record of health-related information on an individual that:

1. Includes patient demographic and clinical health information, such as medical history and problem lists;

2. Has the capacity:

i. To provide clinical decision support;

ii. To support physician order entry;

iii. To capture and query information relevant to health care quality;

iv. To exchange electronic health information with, and integrate such information from other sources;

v. To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

3. Meets the certification criteria adopted by the Secretary at: § 170.314(a)(1) through (8); (b)(1) and (2); (c)(1) and (2); (d)(1) through (8); and (e)(1).

We previously adopted, without modification, the statutory definition of Qualified EHR in regulation (§ 170.102). This was due to our requirement that the definition of CEHRT could only be met if the EHR technology an EP, EH, or CAH had in its possession was certified to all of the general certification criteria and all applicable ambulatory or inpatient setting specific certification criteria. This requirement ensured that EPs', EHs', and CAHs' CEHRT included capabilities related to privacy and security even though the statutory definition of Qualified EHR did not include a requirement for those capabilities. Based on our proposed revised definition of CEHRT, we believe it is necessary now to expand the Base EHR definition to include a capacity that addresses privacy and security.

In Table 6, we explain the certification criteria specified in paragraph (3) of the proposed Base EHR definition. As discussed in section III.A.1 of this preamble, some capabilities within the proposed 2014 Edition EHR certification criteria may only apply to the ambulatory or inpatient setting. For example, to be certified to the proposed ''demographics'' certification criterion (§ 170.314(a)(3)), EHR technology designed for either an ambulatory or inpatient setting would need to enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth (§ 170.314(a)(3)(i)), while EHR technology designed specifically for an inpatient setting would also need to enable a user to electronically record, change, and access the ''date and preliminary cause of death in the event of mortality in accordance with the standard specified in § 170.207(k)'' (§ 170.314(a)(3)(ii)).

In relation to CQMs, we propose that a Base EHR include EHR technology certified to the certification criteria proposed at § 170.314(c)(1) and (2). The inclusion of § 170.314(c)(2) in a Base EHR ensures that EPs, EHs, and CAHs have the capability to incorporate all the data elements of, and calculate, at least one CQM. We anticipate that EHR technology developers would design EHR technology to incorporate the data elements for, and calculate, those CQMs they believe their EHR technology would need to include in order to support the providers to which they market their EHR technology. Therefore, we expect that EHR technology certified to § 170.314(c)(2) would be capable of incorporating all necessary data elements and calculating more than one CQM. This approach may, however, leave a void in the market for EHR technology that would support certain CQMs that EPs, EHs, and CAHs would need to report beginning in 2014.

Accordingly, we are interested in comments on whether we should require certification to a set number of CQMs as part of certification to § 170.314(c)(2). For example, we could require EHR technology designed for the ambulatory setting and that would constitute an EP's Base EHR to be able to incorporate data elements and calculate a specific number of CQMs for each of the CQM ''domains'' proposed by CMS for EPs in the Stage 2 proposed

rule. And for EHR technology designed for the inpatient setting and that would constitute an EH's or CAH's Base EHR, we could require that it be able to incorporate data elements and calculate a minimum threshold number of CQMs proposed by CMS for EHs and CAHs (e.g., 24 or 36). However, we see a potential challenge with this more explicit approach. In order for EPs, EHs, and CAHs to have EHR technology that would meet the definition of a Base EHR, their EHR technology developers could be required to demonstrate that their EHR technology can incorporate and calculate data for certain CQMs that may ultimately be irrelevant to their customers, but nonetheless are necessary for the EHR technology to be certified. We also request comment on whether a Base EHR should include, in addition to § 170.314(c)(1) and (2), the CQM reporting certification criteria proposed at § 170.314(c)(3), which would enable a user to electronically create a data file for transmission of clinical quality measurement results to CMS.

With respect to the ''privacy and security'' certification criteria associated with the capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged, we are proposing that the certification criteria should apply equally to both the ambulatory and inpatient settings. We are, however, interested in public comment on whether there should be a distinction between the ambulatory and inpatient settings for the certification of EHR technology to the privacy and security certification criteria, including for which certification criteria there could be a distinction and the basis for that distinction.

We would like to make clear that the definition of Base EHR is a requirement that must be satisfied to meet the definition of CEHRT. The proposed Base EHR definition is not meant to convey our expectation that EHR technology must be separately certified as a Base EHR. Rather, similar to the proposed revised definition of CEHRT, the definition of a Base EHR can be satisfied through a certified Complete EHR, a single EHR Module certified to all of the certification criteria specified in Table 6 below, or a combination of certified EHR Modules where the resultant combination has been collectively certified to all of the certification criteria specified in Table 6 below. In section IV.D of this preamble, we discuss proposals and options for the representation and marketing of EHR technology that meets the definition of a Base EHR.

Table 6. Certification Criteria Required to Satisfy the Definition of a Base EHR

Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.314(a)(3) Vital Signs § 170.314(a)(4) Problem List § 170.314(a)(5) Medication List § 170.314(a)(6) Medication Allergy List § 170.314(a)(7)
Capacity to provide clinical decision support	Drug-Drug, Drug-Allergy Interaction Checks § 170.314(a)(2) Clinical Decision Support § 170.314(a)(8)
Capacity to support physician order entry	Computerized Provider Order Entry § 170.314(a)(1)
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures § 170.314(c)(1) and (2)
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.314(b)(1) and (2)
	View, Download, and Transmit to 3rd Party § 170.314(e)(1)
Capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged	Privacy and Security § 170.314(d)(1) through (8)

3. Complete EHR

We are proposing to slightly revise the Complete EHR definition for clarity. A Complete EHR is currently defined as ''EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary.'' In the S&CC January 2010 interim final rule, we clarified, based on our understanding of Congress' intent, that the term ''applicable'' in the definition of Certified EHR Technology

meant the adopted certification criteria applicable to either an ambulatory or to an inpatient setting. Therefore, to be certified to the 2011 Edition EHR certification criteria adopted by the Secretary, a Complete EHR designed for an ambulatory setting must meet the mandatory certification criteria adopted at § 170.302 and § 170.304, while a Complete EHR designed for an inpatient setting must meet the mandatory certification criteria adopted under §§ 170.302 and 170.306.

We intend to maintain the concept of a Complete EHR and permit EHR technology developers to seek certification of their EHR technology as Complete EHRs, but propose to revise the definition for clarity. We propose that ''Complete EHR'' mean ''EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting.'' We believe this revised definition is consistent with the previous definition of Complete EHR and clarifies that a Complete EHR can be setting-specific and must meet all adopted mandatory certification criteria for a setting. Our proposed addition of paragraph (d) to § 170.300 clarifies which certification criteria in proposed § 170.314 have general applicability (apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting. This proposed revised definition, if adopted, would be effective upon the final rule's effective date.

While a certified Complete EHR (under the proposed revised definition of CEHRT) will likely have more capabilities than are necessary for any single EP, EH, or CAH to achieve MU, we believe the ''Complete EHR'' designation still has significant market value in that: It provides purchasing clarity and assurance to EPs, EHs, and CAHs that the EHR technology they have meets the regulatory definition of CEHRT; it can support EPs, EHs, and CAHs if they attempt to achieve *all* MU objectives and measures; and it ensures all the capabilities the Complete EHR includes have been tested and certified to work properly together. We believe that the choice to adopt or upgrade a Complete EHR may be more appealing (in some cases for EHs and CAHs and more so for EPs given that there are over 668 certified ambulatory Complete EHRs (which includes newer versions of the *same* Complete EHR)), than having to assume the responsibility to determine which certified EHR Modules include the capabilities needed to support the achievement of MU or having the responsibility to ensure that the certified EHR Modules work properly together.

4. Certifications Issued for Complete EHRs and EHR Modules

Following the S&CC July 2010 final rule's publication, some stakeholders contended that the linkage between a certification issued for an EHR technology and the possession of all of that EHR technology's capabilities should be dropped. In other words, they argued that an EHR technology developer should be able to sell any component of a certified Complete EHR or EHR Module as certified and, equally, that an EP, EH, or CAH should be able to buy something less than 100% of a certified Complete EHR or EHR Module and still be able to say it is using ''certified'' EHR technology. In response to these stakeholder contentions, we issued FAQ 9–10–005–1.[43] This FAQ clarifies that a stand-alone, separate component of a certified Complete EHR cannot derive ''certified'' status based solely on it having been included as part of the Complete EHR when the Complete EHR was certified. This same principle applies to certified EHR Modules with multiple capabilities in that the components of the EHR Modules cannot be separately sold or purchased as certified EHR technology unless they have been separately certified.

We believe that allowing separate components of a certified Complete EHR or certified EHR Module to derive ''certified'' status from the certification of the entire certified Complete EHR or certified EHR Module would undermine the purpose of the ONC HIT Certification Program. In essence, it would permit EHR technology developers to ''*self-declare*'' certifications for components of a certified Complete EHR or certified EHR Module that have never been independently reviewed by an ONC–ACB as actually being able to work as separate, independent technologies. This approach could result in inaccurate, deceptive, or false representations about an EHR technology's capabilities.

It is important for all stakeholders to recognize that a certification is assigned to a Complete EHR or EHR Module, not to a capability. And, in the event that combined and/or workflow-based test procedures are developed, one would be unable to infer that a specific component of a certified Complete EHR or certified EHR Module was compliant with a particular certification criterion unless the component had been separately certified as performing the required capability.

As we have stated in prior rulemakings, Congress made clear that the act of seeking certification must be voluntary. We therefore encourage EHR technology developers to seek, where possible, certification for separate components of a certified Complete EHR or certified EHR Module that would provide the solutions that EPs, EHs, and CAHs seek to adopt. Conversely, EPs, EHs, and CAHs should take note that in some cases it may not be practicable for an EHR technology developer to separate out one or more components for certification without adversely affecting the proper functioning of the remaining components.

5. Adaptations of Certified Complete EHRs or Certified EHR Modules

As the hardware on which EHR technology can run continues to evolve, we expect and encourage EHR technology developers to pursue innovative ways to facilitate efficient workflows and user interactions. In this regard, we believe that it would be possible for an EHR technology developer of a certified Complete EHR or certified EHR Module (and only that EHR technology developer) to create an adaptation of a certified Complete EHR or certified EHR Module without the need for additional certification of the adaptation. We consider an ''adaptation'' of a certified Complete EHR or certified EHR Module to be a software application designed to run on a different medium, which includes the exact same capability or capabilities included in the certified Complete EHR or certified EHR Module. For example, an adaptation of a certified Complete EHR that is capable of running on a tablet device or smart phone could include the capabilities of a certified Complete EHR to e-prescribe, take electronic notes, and manage a patient's active medication list. In this example, the adaptation would be covered by the Complete EHR's certification so long as the adaptation included the full and exact same capabilities required for the particular certification criteria to which the Complete EHR was certified (i.e., in this case, the capabilities required by the certification criteria proposed at § 170.314(b)(3), (a)(9), and (a)(6), respectively)). We note that the user of the adaptation would need to ensure, perhaps through contractual assurances from the EHR technology developer that provides such adaptation, that the adaptation does not introduce privacy

[43] *http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_5/20767.*

and security vulnerabilities into the certified Complete EHR or certified EHR Module.

If an adaptation *does not* make it possible for a user to use the capability or capabilities that were required for the Complete EHR or EHR Module to be certified, then the adaptation could jeopardize an EP's, EH's, or CAH's ability to meet MU because the user of the adaptation would not be meaningfully using EHR technology that had been certified. Furthermore, while an EHR technology developer may create an adaptation without needing to obtain an additional certification, the adaptation would be subject to the provisions of the certification issued for the Complete EHR or EHR Module. ONC–ATCBs and ONC–ACBs maintain authority over the certifications that they issue and can take appropriate action when there is evidence of non-conformance with those certifications. We invite comment on our proposed adaptation policy and whether it strikes an appropriate balance between permitting innovation and providing certainty that the EHR technology used by an EP, EH, or CAH has satisfied the certification criteria adopted by the Secretary.

IV. Provisions of the Proposed Rule Affecting the Permanent Certification Program for HIT (''ONC HIT Certification Program'')

A. Program Name Change

We have established two certification programs, the ''temporary certification program for HIT'' and the ''permanent certification program for HIT'' (see 75 FR 36158 and 76 FR 1262, respectively). The permanent certification program will replace the temporary certification program, which we expect will occur upon the effective date of the final rule that would follow this proposed rule. At that time, there will no longer be a need to continue to differentiate between the certification programs based on their expected duration. Therefore, we propose to replace all references in Part 170 of the Code of Federal Regulations to the permanent certification program with ''ONC HIT Certification Program.'' We believe this new program name provides clear attribution to the agency responsible for the program and an appropriate description of the program's scope, covering both current and potential future activities.

B. ''Minimum Standards'' Code Sets

In § 170.555, we allow ONC–ACBs to certify Complete EHRs and/or EHR Modules to newer versions of certain code sets identified as ''minimum standards'' in Subpart B of part 170 if the Secretary has accepted a newer version for certification and implementation in EHR technology. This approach permits a Complete EHR and/or EHR Module to be certified to a newer version of an adopted code set without the need for additional rulemaking and enables CEHRT to be upgraded with a newer version of an adopted minimum standard code set without adversely affecting its certified status. We finalized two methods through which the Secretary would identify new versions of adopted ''minimum standards'' code sets (76 FR 1294–1295). The first method would allow any member of the general public to notify the National Coordinator about a new version. Under the second method, the Secretary would proactively identify newly published versions. After a new version has been identified, a determination would be issued as to whether the new version constitutes maintenance efforts or minor updates to the adopted code set and consequently may be permitted for use in certification.

The process we have followed involves presenting the identified new version of an adopted ''minimum standard'' code set to the HITSC for assessment, solicitation of public comments on the new version, and issuing a recommendation to the National Coordinator which would identify whether the Secretary's acceptance of the newer version for voluntary implementation and certification would burden the HIT industry, negatively affect interoperability, or cause some other type of unintended consequence. After considering the recommendation of the HITSC, the National Coordinator would determine whether or not to seek the Secretary's acceptance of the new version of the adopted ''minimum standard'' code set. If the Secretary approves the National Coordinator's request, we would issue guidance indicating that the new version of the adopted ''minimum standard'' code set has been accepted by the Secretary.

Our experience has shown that newer versions of the ''minimum standards'' code sets we adopted are issued more frequently than this process can reasonably accommodate. Additionally, based on the ''minimum standard'' code sets we have previously adopted and are proposing in this rule, we believe that permitting EHR technology to be upgraded and certified to newer versions of these code sets would not normally pose an interoperability risk, cause unintended consequences, or place an undue burden on the HIT industry. We propose to revise § 170.555 such that, *unless* the Secretary prohibits the use of a newer version of a ''minimum standard'' code set identified in subpart B of part 170, the newer version could be used voluntarily for certification and implemented as an upgrade to a previously certified Complete EHR or EHR Module without adversely affecting the EHR technology's certified status. We believe this proposed approach would reduce regulatory complexity by providing the industry with the flexibility to utilize newer versions of adopted ''minimum standard'' code sets. In consideration of this proposed new approach we want to clarify that when we refer to a ''newer'' version of a ''minimum standard'' code set, we mean a final version or release as opposed to a draft version or release of a code set.

We expect that we would generally use the same process for determining whether to prohibit the use of a newer version of a ''minimum standard'' code set. The public could inform ONC or the Secretary could proactively identify a newer version of a ''minimum standard'' code set that may not be appropriate for use. We expect that we would still seek a recommendation from the HITSC, based on their assessment of the newer version and on any public comments that they receive, as to whether the Secretary should prohibit the use of the newer version of the ''minimum standard'' code set. After considering the HITSC's recommendation, the National Coordinator would make a recommendation to the Secretary as to whether or not to allow the continued use of the newer version. Finally, if the Secretary decides to prohibit the use of a newer version of a minimum standard code set, we would issue guidance indicating that the newer version of the adopted ''minimum standard'' code set cannot be used for certification under the ONC HIT Certification Program, and thus upgrading previously certified Complete EHRs and EHR Modules to the newer version would adversely affect their certified status.

As an exception to the process outlined above, we believe, in limited circumstances, it may be necessary for the Secretary to act more quickly to prohibit the use of a newer version of a ''minimum standard'' code set. Instances could arise where the use of a newer version of a ''minimum standard'' code set may have an immediate negative effect on interoperability, cause an obvious unintended consequence, or pose an undue burden on the HIT industry. Therefore, under such circumstances, the Secretary may choose to prohibit the

use of a newer version of a ''minimum standard'' code set for purposes of certification and upgrading certified EHR technology without seeking a recommendation from the HITSC in advance.

We propose to also make minor revisions to the text of § 170.555, including removing the terms ''adopted'' and ''accepted'' and replacing the term ''Certified EHR Technology'' in § 170.555(b)(2) with ''A certified Complete EHR or certified EHR Module.'' We believe the revisions provide additional clarity and specificity.

C. Revisions to EHR Module Certification Requirements

1. Privacy and Security Certification

Section 170.550(e) states that ''EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

1. The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

2. An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.''

We propose not to apply the privacy and security certification requirements at § 170.550(e) for the certification of EHR Modules to the 2014 Edition EHR certification criteria. Stakeholder feedback, particularly from EHR technology developers, has identified that this regulatory requirement is causing unnecessary burden (both in effort and cost). EHR Module developers have expressed that they have had to redesign their EHR technology in atypical ways to accommodate this regulatory requirement, which sometimes leads to the inclusion of a privacy or security feature that would not normally be found in a certain type of EHR Module. In turn, this has led to EPs, EHs, and CAHs purchasing EHR Modules that have redundant or sometimes conflicting privacy and security capabilities. Based on our proposal that EPs, EHs, and CAHs must have a Base EHR to meet our proposed revised definition of CEHRT that would apply beginning with FY/CY 2014, we believe that we can be responsive to stakeholder feedback with our proposal not to apply the privacy and security certification requirements at § 170.550(e) for the certification of EHR Modules, while still requiring an equivalent or higher level of privacy and security capabilities to be part of CEHRT.

In section III.B of this preamble, we propose that a Base EHR include all the proposed mandatory privacy and security certification criteria (i.e., all privacy and security certification criteria except the optional ''accounting of disclosure'' certification criterion at § 170.314(d)(9)). This ensures that EPs, EHs, and CAHs have the capabilities to support the MU objective to protect electronic health information created or maintained by CEHRT through the implementation of appropriate technical capabilities. In addition, EPs, EHs, and CAHs remain responsible for implementing their EHR technology in ways that meet applicable privacy and security requirements under Federal and applicable State law (e.g., the HIPAA Privacy Rule and Security Rule and 42 CFR Part 2). These factors reduce the importance of certifying EHR Modules to all of the privacy and security certification criteria or requiring EHR Module developers to demonstrate that privacy and security certification criteria are inapplicable to or technically infeasible to implement for their EHR Modules. Thus, a regulatory burden and associated costs for EHR Module developers would be eliminated, and EPs, EHs, and CAHs would not have to purchase EHR Modules that have privacy and security capabilities that are redundant or conflict with the capabilities of the EHR technology that would make up their Base EHR.

2. Certification to Certain New Certification Criteria

As discussed in section III.A of this preamble, we propose to adopt new 2014 Edition EHR certification criteria that would require the following: Electronic recording of the numerator for each MU objective with a percentage-based measure (§ 170.314(g)(1) ''automated numerator recording''); electronic recording of activities related to non-percentage-based measures (§ 170.314(g)(3) ''non-percentage-based measure use report''); and user-centered design processes to be applied to EHR technology that includes certain capabilities (§ 170.314(g)(4) ''safety-enhanced design''). To ensure proper certification of EHR Modules to these proposed certification criteria, we propose to revise § 170.550.

We propose to revise § 170.550 to ensure that EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure are certified to proposed § 170.314(g)(1). However, we propose that this requirement would not apply if the EHR Module was certified to § 170.314(g)(2) (automated measure calculation) in lieu of certification to § 170.314(g)(1). We propose to revise § 170.550 in order to ensure that EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a non-percentage-based measure are certified to proposed § 170.314(g)(3). We propose to revise § 170.550 to ensure that EHR Modules presented for certification to any of the certification criteria listed in proposed § 170.314(g)(4) are also certified to § 170.314(g)(4). We propose to include these three revisions at § 170.550(f).

D. ONC–ACB Reporting Requirements

In the permanent certification program final rule (76 FR 1318–1323), we adopted (§ 170.523) principles of proper conduct to which ONC–ACBs must adhere for their authorization to remain in good standing under the program. The principle of proper conduct at § 170.523(f) requires an ONC–ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified which includes, at a minimum: The Complete EHR or EHR Module developer name (if applicable); the date certified; the product version; the unique certification number or other specific product identification; the clinical quality measures to which a Complete EHR or EHR Module has been certified; where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion adopted by the Secretary; and where applicable, the certification criterion or certification criteria to which each EHR Module has been certified.

We propose to require that ONC–ACBs include an additional data element in the set of data they are required to provide regarding the Complete EHRs and/or EHR Modules they report as certified to ONC under § 170.523(f). Specifically, we propose that an ONC–ACB would need to provide to ONC a hyperlink for each

Complete EHR and EHR Module it certifies that would enable the public to access the test results that the ONC–ACB used to certify the EHR technology. As with all of the other data an ONC–ACB reports to ONC regarding a Complete EHR or EHR Module it certifies, we would make the hyperlink available on the CHPL with the respective certified Complete EHR or certified EHR Module. As with other records related to certification, we expect that ONC–ACBs would ensure the functionality of the hyperlink for a minimum of five years consistent with § 170.523(g), unless a certified Complete EHR or certified EHR Module is removed from the CHPL. Under such circumstances, the ONC–ACB would no longer need to ensure the functionality of the hyperlink, although retention of the test results would be required. We believe this additional element is important to increase transparency in the testing and certification processes and would serve to make more information available to prospective purchasers of certified Complete EHRs and certified EHR Modules as well as other stakeholders.

E. Continuation and Representation of Certified Status

1. 2011 or 2014 Edition EHR Certification Criteria Compliant

In our certification program final rules (76 FR 1302, 75 FR 36189), we indicated that we anticipated adopting new and/or revised certification criteria every two years to coincide with changes to the MU objectives and measures under the EHR Incentive Programs. We did not, however, set a specific *expiration* date for certifications. Rather, we explained that once the Secretary adopts new and/or revised certification criteria, EHR technology may need to be tested and certified again. In other words, the previous certifications may no longer accurately represent what is required to meet the adopted certification criteria. Based on this expectation, we established in the Permanent Certification Program final rule and at § 170.523(k) that ONC–ACBs must require as part of certification that EHR technology developers include on their Web sites and in all marketing materials, communications, statements, and other assertions, the years (''20[XX]/20[XX]'') for which a certification issued for a Complete EHR or EHR Module would be considered compliant. Again, anticipating that every two years certification criteria would be adopted and EHR technology would need to be certified to the certification criteria to meet the definition of CEHRT, we clarified this provision in the Permanent Certification Program final rule with examples (76 FR 1305). These examples indicated that EHR technology certified to the adopted certification criteria (i.e., the certification criteria adopted at §§ 170.302, 170.304, and 170.306) would include ''2011/2012'' compliant and that certifications based on certification criteria adopted through future rulemaking would indicate ''2013/2014'' compliant.

In this proposed rule, we have referred to the adopted certification criteria collectively as the ''2011 Edition EHR certification criteria'' and the certification criteria proposed in this rule collectively as the ''2014 Edition EHR certification criteria'' (terms we also propose to include as defined terms in § 170.102). In line with this convention, we propose to revise § 170.523(k) to require the *edition* of certification criteria for which a certification issued for a Complete EHR or EHR Module would be considered compliant instead of the years (i.e., ''2014 Edition EHR certification criteria compliant).'' This proposed revision would apply to all certifications issued after the effective date of a final rule. We believe this proposal would further assist in eliminating confusion about the ''expiration'' of certifications, align with our proposed revised definition of CEHRT, and provide the market with greater clarity regarding the capabilities of certified Complete EHRs and certified EHR Modules.

For certified EHR technologies that are already designated as ''2011/2012'' compliant, we have considered multiple options and concluded that the best approach is to *not require* any changes to the ''2011/2012'' designation, such as having them re-designated as ''2011 Edition EHR certification criteria compliant.'' Rather, we would simply make clear that certified Complete EHRs and certified EHR Modules that are designated as ''2011/2012'' compliant would remain valid for purposes of the EHR reporting periods in FY/CY 2013. We believe this approach minimizes the burden on EHR technology developers. We request public comment on our approach and any other approach that would present the least burden for EHR technology developers and the least confusion for the market.

Section 170.523(k)(1)(i) states, in part, that ''[A] certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.'' We propose to revise this statement by removing ''* * * or guarantee the receipt of incentive payments'' because although incentives will be available under the Medicaid EHR Incentive Program until 2021, they will no longer be available under the Medicare EHR Incentive Program after 2016. Therefore, to prevent confusion and to defer to CMS in establishing and specifying the parameters of the EHR Incentive Programs, we propose this revision to the statement.

2. Updating a Certification

To ensure that the information required by § 170.523(k)(1)(i) remains accurate and reflects the correct edition of EHR certification criteria, ONC–ACBs, under § 170.550(d), are permitted to provide updated certifications to previously certified EHR Modules under certain circumstances. In the Permanent Certification Program final rule (76 FR 1306) and at § 170.502, we defined ''providing or provide an updated certification'' to an EHR Module as ''the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).'' Based on our proposal to not apply the privacy and security certification requirements at § 170.550(e) to EHR Modules certified to the proposed 2014 Edition EHR certification criteria, we propose to revise the definition of ''providing or provide an updated certification'' to eliminate the requirement that ONC–ACBs would need to verify that any new privacy and security certification criteria apply when they issue an updated certification. However, ONC–ACBs would still need to verify whether the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

The certification criteria and certification requirements that apply to previously certified EHR Modules may change with each new edition of certification criteria that is adopted by the Secretary. Therefore, we believe that we can provide the best guidance to stakeholders on when ''updating'' a certification would be permitted with each rulemaking for an edition of certification criteria. For the 2014 Edition EHR certification criteria, if we were to adopt in a final rule all the proposed new certification criteria discussed above in section IV.C.2

(''Certification to Certain New Certification Criteria'') of this preamble, then no previously certified EHR Modules could be issued updated certifications because every EHR Module would require certification to, at a minimum, the certification criterion at § 170.314(g)(1) (automated numerator recording) (or § 170.314(g)(2) in lieu of being certified to § 170.314(g)(1)) or the certification criterion at § 170.314(3) (non-percentage-based measure use report). Although ONC–ACBs would not be able to issue updated certifications to the 2014 Edition EHR certification criteria, ''updating'' certifications may still be a viable option under certain conditions when the Secretary adopts another edition of certification criteria in the future.

3. Base EHR Representation

An EHR technology developer's Complete EHR, single EHR Module or combination of EHR Modules could constitute a Base EHR by meeting all the certification criteria required by the definition of Base EHR for the ambulatory setting or inpatient setting. We believe EPs, EHs, and CAHs would benefit from knowing which certified EHR technologies on the market constitute a Base EHR because they would need to have a Base EHR to satisfy the proposed revised definition of CEHRT beginning with FY/CY 2014. We do not believe that it is necessary to expressly propose a requirement for ONC–ACBs related to the identification of EHR technology that meets the definition of a Base EHR. To gain a competitive advantage in the market, we believe EHR technology developers would likely identify on their Web sites and in marketing materials, communications, statements, and other assertions whether their certified Complete EHR or EHR Module(s) meet the definition of a Base EHR (designed for either the ambulatory or inpatient setting). However, we considered as a potential alternative or complementary approach to permit ONC–ACBs when issuing certifications to Complete EHRs and EHR Modules that meet the definition of a Base EHR to formally indicate such fact to the EHR technology developer and permit the EHR technology developer in association with its EHR technology's certification to represent that the EHR technology meets the definition of a Base EHR. We welcome comments on these and any other approaches that we have not identified.

V. Request for Additional Comments

A. Certification and Certification Criteria for Other Health Care Settings

The HITECH Act did not authorize the availability of incentives under the EHR Incentive Programs for all health care providers. Consequently, the certification criteria proposed for adoption in this rule focus primarily on enabling EHR technology to be certified and subsequently adopted and used by EPs, EHs, and CAHs who seek to demonstrate MU under the EHR Incentive Programs.

In the Permanent Certification Program final rule (76 FR 1294), we discussed the National Coordinator's statutory authority to establish a voluntary certification program or programs for other types of HIT besides EHR technology. However, as explained in the Permanent Certification Program final rule, any steps towards certifying other types of HIT, including EHR technology such as ''Complete EHRs'' or ''EHR Modules'' for settings other than inpatient or ambulatory, would first require the Secretary to adopt certification criteria for other types of HIT and/or other types of health care settings.

As we continue to adopt new and revised certification criteria to support MU, we believe that it is prudent to seek public comment on whether we should focus our efforts on the certification of the HIT used by health care providers that are ineligible to receive incentives under the EHR Incentive Programs. In particular, we are interested in commenters' thoughts on whether we should consider adopting certification criteria for other health care settings, such as the long-term care, post-acute care, and mental and behavioral health settings. For those commenters that believe we should consider certification criteria for other health care settings, we respectfully request that their comments specify the certification criteria that would be appropriate as well as the benefits they believe a regulatory approach would provide. Last, we ask that the public consider whether the private sector could alternatively address any perceived need or demand for such certification. For example, we are aware that the Certification Commission for Health Information Technology (CCHIT) has certification programs for long-term and post-acute care as well as behavioral health EHR technology.[44]

B. 2014 Edition EHR Accounting of Disclosures Certification Criterion

We previously adopted an ''accounting of disclosures'' optional certification criterion for the 2011 Edition EHR certification criteria (§ 170.302(w)), which requires EHR technology to be capable of electronically recording disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d) (''*Record treatment, payment, and health care operations disclosures.* The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501''). We are proposing to adopt this same certification criterion as an optional certification criterion for the 2014 Edition EHR certification criteria (§ 170.314(d)(9)), but are requesting public comment on whether we should adopt a revised certification criterion. Since publication of the S&CC July 2010 final rule, the HHS Office for Civil Rights issued a proposed rule (76 FR 31426) addressing the changes required by section 13405(c) of the HITECH Act, including changes to the accounting of disclosure requirements under the HIPAA Privacy Rule.[45] We are interested in whether commenters believe that the 2014 Edition EHR certification criterion for ''accounting of disclosures'' should be revised to be a mandatory certification criterion. We are also interested in whether commenters think that the 2014 Edition EHR certification criterion should be revised to include capabilities that would more fully support an EP's, EH's, and CAH's ability to comply with the current HIPAA Privacy Rule accounting for disclosure requirements at 45 CFR 164.528. Additionally, we are interested in receiving input on whether, and what additional, changes to the certification criterion would be needed to support compliance with the proposed HIPAA Privacy Rule accounting for disclosure provisions, if they were to be adopted by final rule in substantially the same form as they were proposed. For those commenters that believe revisions are appropriate, we respectfully request that their comments identify whether the certification criterion should be changed from optional to mandatory and identify the specific capabilities that the certification criterion should include

[44] *http://www.cchit.org/get_certified/cchit-certified-2011.*

[45] *http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-13297.pdf.*

and the rationale for including those capabilities.

C. Disability Status

We are interested in whether commenters believe that EHR technology certified to the 2014 Edition EHR certification criteria should be capable of recording the functional, behavioral, cognitive, and/or disability status of patients (collectively referred to as ''disability status''). The recording of disability status could have many benefits. It could facilitate provider identification of patients with disabilities and the subsequent provision of appropriate auxiliary aids and services for those patients by providers. It could also promote and facilitate the exchange of this type of patient information between providers of care, which could lead to better quality of care for those with disabilities. Further, the recording of disability status could help monitor disparities between the ''disabled'' and ''nondisabled'' population.

We are specifically requesting comment on whether there exists a standard(s) that would be appropriate for recording disability status in EHR technology. We are aware of a standard for disability status approved by the Secretary for use in population health surveys sponsored by HHS [46] and standards under development as part of the Standards and Interoperability Framework and the Continuity Assessment Record and Evaluation (CARE) assessment tool.[47] We welcome comments on whether these standards or any other standards would be appropriate for recording disability status in EHR technology.

We ask that commenters consider whether the recording of disability status should be a required or optional capability that EHR technology would include for certification to the 2014 Edition EHR certification criteria. We also ask commenters to consider whether the recording of disability status should be part of a Base EHR and included in a separate certification criterion or possibly the ''demographics'' certification criterion (§ 170.314(a)(3)). Last, we ask commenters to consider whether disability status recorded according to the standard should also be included in other certification criteria such as ''transitions of care—incorporate summary care record'' (§ 170.314(b)(1)), ''transitions of care—create and transmit summary care record'' (§ 170.314(b)(2)), ''view, download and transmit to 3rd party'' (§ 170.314(e)(1)), and ''clinical summaries'' (§ 170.314(e)(2)).

D. Data Portability

We seek public comment on whether we should adopt a certification criterion that focuses on the portability of data stored within CEHRT. When a provider seeks to change EHR technology, we believe that they should have the ability to easily switch EHR technology—at a low cost—and migrate most or all of their data in structured form to another EHR technology. In the absence of this capability, providers may be ''locked-in'' to their current EHR technology. This could ultimately impede innovation and is a key aspect of the EHR technology market that requires significant maturity. With these considerations, we seek responses to the following questions:

1. Is EHR technology capable of electronically providing a sufficient amount of a patient's health history using summary of care records formatted according to the Consolidated CDA for the scenario described above?

2. Is all of the data in a provider's EHR #1 necessary to migrate over to EHR #2 in the event the provider wants to switch? We recognize that medical record retention laws affect the provider's overall approach in terms of a full archived data set, but our question seeks to determine whether the loss of some data would be tolerable and if so, which data?

3. Considering the standards we have adopted and propose for adoption in this rule, we request comment on what additional standards and guidance would be necessary to meet these market needs for data portability, including the portability of administrative data such as Medicare and Medicaid eligibility and claims. Additionally, we are interested in commenters' thoughts related to an incremental approach where a specific set of patient data could be used as a foundation to improve data portability for the situation described above as well as other situations.

4. Does the concept of a capability to batch export a single patient's records (or a provider's entire patient population) pose unintended consequences from a security perspective? What factors should be considered to mitigate any potential abuse of this capability, if it existed?

E. EHR Technology Price Transparency

Section 170.523(k)(3) requires that when an ONC–ACB issues a certification to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part, the certification must be separate and distinct from any other certification(s) based on other criteria or requirements (such as those not part of the ONC HIT Certification Program). During implementation of the temporary certification program, we have received feedback from stakeholders that some EHR technology developers do not provide clear price transparency related to the full cost of a certified Complete EHR or certified EHR Module. Instead, some EHR technology developers identify prices for multiple groupings of capabilities even though the groupings do not correlate to the capabilities of the entire certified Complete EHR or certified EHR Module. Thus, with the transparency already required by § 170.523(k)(3) in mind, we believe that the EHR technology market could benefit from transparency related to the price associated with a certified Complete EHR or certified EHR Module. We believe price transparency could be achieved through a requirement that ONC–ACBs ensure that EHR technology developers include clear pricing of the full cost of their certified Complete EHR and/or certified EHR Module on their Web sites and in all marketing materials, communications, statements, and other assertions related to a Complete EHR's or EHR Module's certification. Put simply, this provision would require EHR technology developers to disclose only the full cost of a certified Complete EHR or certified EHR Module. It would in no way dictate the price an EHR technology developer could assign to its EHR technology, just that a single price for all the capabilities in the certified Complete EHR or certified EHR Module be made publicly available. We believe price transparency would provide purchasing clarity for health care providers and lead to more competitive EHR technology pricing. We request comment on the feasibility and value of price transparency for certified Complete EHRs and certified EHR Modules in the manner described.

VI. Response to Comments

Because of the large number of public comments normally received in response to **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

[46] *http://www.minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlid=208.*

[47] *http://wiki.siframework.org/file/detail/CARE+Tool+Functional%2C+Cognitive+and+Skin+Status.xls.*

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by the Office of Management and Budget, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. To comment on the collection of information or to obtain copies of the supporting statements and any related forms for the proposed paperwork collections referenced in this section, email your comment or request, including your address and phone number to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

Abstract

Under the permanent certification program, accreditation organizations that wish to become the ONC-Approved Accreditor (ONC-–AA) must submit certain information, organizations that wish to become an ONC-Authorized Certification Bodies (ONC–ACBs) must submit the information specified by the application requirements, and ONC–ACBs must comply with collection and reporting requirements, records retention requirements, and submit annual surveillance plans and annually report surveillance results.

In the Permanent Certification Program final rule (76 FR 1312–14), we solicited public comment on each of the information collections associated with the requirements described above (and included in regulation at 45 CFR 170.503(b), 170.520, and 170.523(f), (g), and (i), respectively). These collections of information are currently approved under OMB control number 0990–0378. In this proposed rule, we seek to revise § 170.523(f) and, correspondingly, seek to revise the approved collection of information by requiring ONC–ACBs to include one additional data element in the list of information about Complete EHRs and EHR Modules they report to ONC.

Section 170.523(f) requires an ONC–ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified as well as certain minimum information about each certified Complete EHR and/or EHR Module. We propose to require ONC–ACBs to additionally report to ONC a hyperlink with each EHR technology they certify that provides the public with the ability to access the test results used to certify the EHR technology. We propose to add this requirement at § 170.523(f)(8).

For the purposes of estimating this additional potential burden, we have used the following assumptions. We assume that all of the estimated applicants will apply and become ONC–ACBs (i.e., 6 applicants) and that they will report weekly (i.e., respondents will respond 52 times per year). We assume an equal distribution among ONC–ACBs in certifying EHR technology on a weekly basis. As such, based on the number of Complete EHRs and EHR Modules listed on the CHPL at the end of September of 2011 (approximately one year since the CHPL's inception), we estimate that, on average, each ONC–ACB will report 4 test results hyperlinks to ONC on a weekly basis.

We believe it will take approximately 5 minutes to report each hyperlink to ONC. Therefore, as reflected in the table below, we estimate an additional 20 minutes of work per ONC–ACB each week. Under the regulatory impact statement section, we discuss the estimated costs associated with reporting the hyperlinks to ONC.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 170.523(f)(8)	6	52	.33	103

With the additional proposed collection of information at § 170.523(f)(8), we believe 103 burden hours will be added to our burden estimate in OMB control number 0990–0378. Our estimates for the total burden hours under OMB control number 0990–0378 are expressed in the table below.

ESTIMATED ANNUALIZED TOTAL BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 170.503(b)	2	1	1	2
45 CFR 170.520	6	1	1	6
45 CFR 170.523(f)	6	52	1.33	415
45 CFR 170.523(g)	n/a	n/a	n/a	n/a
45 CFR 170.523(i)	6	2	1	12

ESTIMATED ANNUALIZED TOTAL BURDEN HOURS—Continued

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Total burden hours for OMB control number 0990–0378	.....	.....	.....	435

VIII. Regulatory Impact Statement

A. Statement of Need

Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria. On January 13, 2010, the Department issued an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria. On July 28, 2010, the Department published in the **Federal Register** a final rule to complete the adoption of the initial set of standards, implementation specifications, and certification criteria. This proposed rule is being published to revise previously adopted standards, implementation specifications, and certification criteria and to propose the adoption of new standards, implementation specifications, and certification criteria in order to support future MU Stages' objectives and measures. Certification criteria and associated standards and implementation specifications will be used to test and certify Complete EHRs and EHR Modules in order to make it possible for EPs, EHs, and CAHs to adopt and implement CEHRT. EPs, EHs, and CAHs who seek to qualify for incentive payments under the EHR Incentive Programs are required by statute to use CEHRT.

B. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

1. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this proposed rule is not an economically significant rule because we estimate that the costs to prepare Complete EHRs and EHR Modules to be tested and certified will be less than $100 million per year. Nevertheless, because of the public interest in this proposed rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the proposed rule.

a. Costs

This rule proposes the adoption of standards, implementation specifications, and certification criteria that would establish the capabilities that EHR technology would need to demonstrate to be certified. Our analysis focuses on the direct effects of the provisions of this proposed rule—the costs incurred by EHR technology developers to develop and prepare Complete EHRs and EHR Modules to be tested and certified in accordance with the certification criteria adopted by the Secretary. That is, we focus on the technological development and preparation costs necessary for a Complete EHR or EHR Module already certified to the 2011 Edition EHR certification criteria to upgrade to the proposed 2014 Edition EHR certification criteria and for developing a new Complete EHR or EHR Module to meet the 2014 Edition EHR certification criteria. The estimated costs for having EHR technology actually tested and certified were discussed in the permanent certification program final rule (76 FR 1318–23). Last, we estimate the costs for ONC–ACBs to develop and report to ONC hyperlinks to the test results used to certify EHR technology.

i. Development and Preparation Costs for 2014 Edition EHR Certification Criteria

The development costs we estimate are categorized based on the type of certification criteria discussed in this proposed rule (i.e., new, revised, and unchanged). The numbers of Complete EHRs and EHR Modules that we estimate would be tested and certified to each certification criteria are based on the statistics we obtained from the CHPL on September 11, 2011. We attempted to identify the total number of unique Complete EHRs and EHR Modules that had been certified to the 2011 Edition EHR certification criteria as of September 11th. By this we mean that we attempted to discern how many Complete EHRs and EHR Modules were certified that would not constitute a newer version of the same EHR technology. Using this number, we have adjusted it based on additional considerations such as our proposals related to optional certification criteria, to the Base EHR certification criteria, and to our revised definition of CEHRT. The proposed revised CEHRT definition would only require EPs, EHs, and CAHs to possess the CEHRT they need to demonstrate MU for the stage they seek to accomplish, which could conceivably directly affect the number of EHR technologies developed to certain certification criteria that support MU menu objectives and measures. Using the final estimate of Complete EHRs and EHR Modules that we believe will be certified to each certification criterion, we have then created an estimated range of 10% less and 10% more EHR technologies being developed to each 2014 Edition EHR certification criterion. We believe this will account for potential new entrants to the market, as well as for those EHR technologies tested and certified to the 2011 Edition EHR certification criteria that may not be tested and certified to the 2014 Edition EHR certification criteria because of such factors and company mergers or acquisitions and the loss of market share for some Complete EHRs and EHR Modules. For unchanged certification criteria, we have only calculated development and preparation costs for a potential 10% increase in new EHR technologies being developed and prepared to meet the certification criteria since there would not be any costs associated with upgrading EHR technologies previously certified to the 2011 Edition EHR certification criteria.

We are not aware of an available independent study (e.g., a study capturing the efforts and costs to develop and prepare Complete EHRs and EHR Modules to meet the requirements of the 2011 Edition EHR certification criteria) that we could rely upon as a basis for estimating the efforts and costs required to develop and prepare EHR technology to meet the 2014 Edition EHR certification criteria. Therefore, we have relied upon our own research to estimate the effort required to develop and prepare EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. We have identified 3 levels of effort that we believe can be associated with the development and preparation of EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. These levels of effort are the *average* range of hours we would expect to be necessary to develop EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. This means that a few EHR technology developers' costs may be less than this range and a few may exceed the range. Level 1 is for certification criteria that we believe will require the least amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 40–100 hours. Level 2 is for certification criteria that we believe will require a moderate amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 100–300 hours. Level 3 is for certification criteria that we believe will require the most amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 300–400 hours.

We have based the effort levels on the hours necessary for a software developer to develop and prepare the EHR technology for testing and certification. The U.S. Department of Labor, Bureau of Labor Statistics estimates that the mean hourly wage for a software developer is $43.47.[48] We have also calculated the costs of an employee's benefits. We have calculated these costs by assuming that an employer expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. We have rounded up the average software developer's wage with benefits to $60 per hour.

To calculate our low cost estimates for each certification criterion in the tables below, we have multiplied the low number of the estimated range of EHR technologies expected to be developed and prepared by the low number of estimated hours for a software developer to develop and prepare the EHR technologies for testing and certification. To calculate our high cost estimates for each certification criterion in the tables below, we have multiplied the high number of the estimated range of EHR technologies expected to be developed and prepared to the criterion by the high number of estimated hours for a software developer to develop and prepare the EHR technologies for testing and certification. For the following tables (Tables 7 through Table 13), dollar amounts are expressed in 2012 dollars.

New Certification Criteria

TABLE 7—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(a)(9)	Electronic notes	420–514	1.01	3.08
170.314(a)(13)	Family health history	420–514	1.01	3.08
170.314(b)(3)	Electronic prescribing (inpatient)	101–123	.24	.74
170.314(f)(7)	Cancer case information	320–392	.77	2.35
170.314(g)(3)	Non-percentage-based measure use report	567–693	1.36	4.16
Total			4.39	13.41

TABLE 8—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(a)(12)	Imaging	420–514	2.52	9.25
170.314(b)(6)	Transmission of electronic laboratory tests and values/results to ambulatory providers.	146–178	.88	3.20
170.314(d)(4)	Amendments	566–691	3.40	12.44
170.314(e)(3)	Secure messaging	320–392	1.92	7.06
170.314(f)(8)	Transmission to cancer registries	320–392	1.92	7.06
170.314(g)(1)	Automated numerator recording	398–486	2.39	8.75
Total			13.03	47.76

[48] *http://www.bls.gov/oes/current/oes151132.htm.*

TABLE 9—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 3 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(a)(17)	Electronic medication administration record	101–123	1.82	2.95
170.314(e)(1)	View, download, and transmit to 3rd party	567–693	10.21	16.63
170.314(g)(4)	Safety-enhanced design	567–693	10.21	16.63
Total			22.24	36.21

Revised Certification Criteria

TABLE 10—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(a)(2)	Drug-drug, drug-allergy interaction checks	420–514	1.01	3.08
170.314(a)(3)	Demographics	460–562	1.10	3.37
170.314(a)(5)	Problem list	438–536	1.05	3.22
170.314(a)(16)	Patient-specific education resources	421–515	1.01	3.09
170.314(b)(3)	Electronic prescribing (ambulatory)	328–400	.79	2.40
170.314(b)(5)	Incorporate laboratory tests and values/results (ambulatory setting)	277–339	.66	2.03
170.314(c)(2)	Clinical quality measures—incorporate and calculate	379–463	.91	2.78
170.314(d)(3)	Audit report(s)	567–693	1.36	4.16
170.314(e)(2)	Clinical summaries	314–384	.75	2.30
170.314(f)(2)	Transmission to immunization registries	382–466	.92	2.80
170.314(f)(4)	Transmission to public health agencies	373–455	.90	2.73
170.314(f)(6)	Transmission of reportable laboratory tests and values/results	63–77	.15	.46
Total			10.61	32.42

TABLE 11—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(b)(1)	Transitions of care—incorporate summary care record	381–465	2.29	8.37
170.314(b)(4)	Clinical information reconciliation	434–530	2.60	9.54
170.314(c)(3)	Clinical quality measures—reporting	379–463	2.27	8.33
170.314(d)(2)	Auditable events and tamper resistance	567–693	3.40	12.47
170.314(d)(7)	Encryption of data at rest	566–691	3.40	12.44
170.314(g)(2)	Automated measure calculation	396–484	2.21	8.71
Total			16.17	59.86

TABLE 12—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 3 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(a)(8)	Clinical decision support	409–501	7.36	12.02
170.314(b)(2)	Transitions of care—create and transmit	381–465	6.86	11.16
170.314(c)(1)	Clinical quality measures—capture and export	379–463	6.82	11.11
Total			21.04	34.29

Unchanged Certification Criteria

TABLE 13—2014 EDITION UNCHANGED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs	
			Low ($M)	High ($M)
170.314(a)(1)	CPOE	42	.25	.76
170.314(a)(4)	Vital signs, body mass index, and growth charts	48	.29	.86
170.314(a)(6)	Medication list	50	.30	.90
170.314(a)(7)	Medication allergy list	50	.30	.90
170.314(a)(10)	Drug-formulary checks	47	.28	.85
170.314(a)(11)	Smoking status	50	.30	.90
170.314(a)(14)	Patient lists	46	.28	.83
170.314(a)(15)	Patient reminders	36	.22	.65
170.314(a)(18)	Advance directives	11	.07	.20
170.314(b)(5)	Incorporate laboratory tests and values/results (inpatient setting)	16	.10	.29
170.314(d)(1)	Authentication, access control, and authorization	64	.38	1.15
170.314(d)(5)	Automatic log-off	63	.38	1.13
170.314(d)(6)	Emergency access	62	.37	1.12
170.314(d)(8)	Integrity	63	.38	1.13
170.314(d)(9)	Accounting of disclosures	15	.09	.27
170.314(f)(1)	Immunization information	42	.25	.76
170.314(f)(3)	Public health surveillance	41	.25	.74
170.314(f)(5)	Reportable laboratory tests and values/results	7	.04	.13
Total			4.53	13.57

ii. Overall Development and Preparation Costs Over a 3-year Period

In total, we estimate the overall costs for a 3-year period to be $92.01 million to $237.52 million, with a cost mid-point of approximately $164.77 million. If we were to evenly distribute the overall costs to develop and prepare Complete EHRs and EHR Modules between calendar years 2012 and 2014, we believe they would likely be in the range of $30.67 million to $79.17 million per year with an annual cost mid-point of approximately $54.92 million. However, we do not believe that the costs will be spread evenly over these three years due to market pressures to have certified Complete EHRs and certified EHR Modules ready and available prior to when EPs, EHs, and CAHs must meet the proposed revised definition of CEHRT for FY/CY 2014. We assume this factor will cause a greater number of developers to prepare EHR technology for testing and certification towards the end of 2012 and throughout 2013, rather than in 2014. As a result, we believe as represented in Table 14 that the costs attributable to this proposed rule will be distributed as follows: 40% for 2012, 50% for 2013, and 10% for 2014. The dollar amounts expressed in Table 14 are expressed in 2012 dollars.

TABLE 14.— DISTRIBUTED TOTAL PREPARATION COSTS FOR COMPLETE EHR AND EHR MODULE DEVELOPERS (3 YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2012	40	36.80	95.01	65.91
2013	50	46.01	118.76	82.38
2014	10	9.20	23.75	16.48
3-Year Totals		92.01	237.52	167.53

iii. Costs for Reporting Test Results Hyperlinks

Costs to ONC–ACBs

Under § 170.523(f)(8), ONC–ACBs will be required to provide ONC, no less frequently than weekly, a hyperlink with each EHR technology it certifies that provides the public with the ability to access the test results used to certify the EHR technology. As stated in the collection of information section, we will require the reporting of this information on a weekly basis and that it will take each ONC–ACB about 20 minutes to prepare and electronically transmit an estimated four test results hyperlinks with the other required information to ONC each week.

We believe that an employee equivalent to the Federal Classification of GS–9 Step 1 could report the hyperlink to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC, as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the specified tasks. We have calculated these costs by assuming that an ONC–ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 15 below and are expressed in 2012 dollars.

TABLE 15—ANNUAL COSTS FOR AN ONC–ACB TO REPORT TEST RESULTS HYPERLINKS TO ONC

Program requirement	Employee equivalent	Annual burden hours per ONC–ACB	Employee hourly wage rate	Employee Benefits Hourly Cost	Total cost per ONC–ACB
45 CFR 170.523(f)(8)	GS–9 Step 1	17.16	$22.39	$8.06	$522.52

To estimate the highest possible cost, we assume that all of the estimated applicants (i.e., six) that we anticipate will apply under the permanent certification program will become ONC–ACBs. Therefore, we estimate the total annual development and reporting cost for under the permanent certification program to be $3,136 (rounded using a total of 103 hours).

Costs to the Federal Government

We do not believe that we will incur any additional costs to post test results hyperlinks than the costs we estimated for posting a list of all certified Complete EHRs and EHR Modules on our Web site (i.e., the CHPL), which was $10,784 on an annualized basis (76 FR 1323).

b. Benefits

We believe that there will be several benefits that may arise from this proposed rule. Foremost, the proposed 2014 Edition EHR certification criteria include the capabilities that CEHRT must have to support EPs', EHs', and CAHs' attempts to demonstrate MU and qualify for incentive payments under the EHR Incentive Programs. Additionally, by adopting the proposed new and revised certification criteria, the interoperability, functionality, utility, and security of EHR technology will be further enhanced. The capabilities specified in the adopted certification criteria will help ensure that health care providers have the necessary information technology tools to improve patient care, and reduce medical errors and unnecessary tests. The standards adopted will aid in fostering greater interoperability. The proposals in this proposed rule would increase the competition and innovation in the HIT marketplace that was spurred by the Secretary's adoption of the 2011 Edition EHR certification criteria. The proposals to revise the definition of CEHRT, the process for approving newer versions of minimum standards, and the privacy and security certification of EHR Modules will reduce the regulatory burden and add flexibility for EHR technology developers, EPs, EHs, and CAHs. Further, the proposed splitting of certification criteria into multiple certification criteria should increase the opportunity and flexibility for EHR technology developers to have more EHR technology eligible for certification. Last, we believe the proposals in this proposed rule will be supportive of other initiatives, such as the Partnership for Patients.

2. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities.

The Small Business Administration (SBA) establishes the size of small businesses for Federal government programs based on average annual receipts or the average employment of a firm. While Complete EHRs and EHR Module developers represent a small segment of the overall information technology industry, we believe that the entities impacted by this proposed rule most likely fall under the North American Industry Classification System (NAICS) code 541511 ''Custom Computer Programming Services'' specified at 13 CFR 121.201 where the SBA publishes ''Small Business Size Standards by NAICS Industry.'' The SBA size standard associated with this NAICS code is set at $25 million in annual receipts [49] which ''indicates the maximum allowed for a concern and its affiliates to be considered small entities.''

Based on our analysis, we believe that there is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard, but note that the available data does not show how many of these entities will develop a Complete EHR or EHR Module. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many Complete EHR and EHR Module developers are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of the Complete EHR and EHR Module developers to correlate to the SBA size standard. However, although not correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of EHR technology developers that have had Complete EHRs and/or EHR Modules certified to the 2011 Edition EHR certification criteria have less than 51 employees.

We estimate that this proposed rule would have effects on Complete EHR and EHR Module developers, some of which may be small entities. However, we believe that we have proposed the minimum amount of requirements necessary to accomplish our policy goals, including a reduction in regulatory burden and additional flexibility for the regulated community; and that no additional appropriate regulatory alternatives could be developed to lessen the compliance burden associated with this proposed rule. In order for a Complete EHR or EHR Module to provide the capabilities that an EP, EH, or CAH would be required to use under the EHR Incentive Programs Stage 2 final rule, it will need to comply with the applicable certification criteria adopted by the Secretary. Moreover, we note that this proposed rule does not impose the costs cited in the regulatory impact analysis as compliance costs, but rather as investments which Complete EHR and EHR Module developers voluntarily take on and expect to recover with an appropriate rate of return. Accordingly, we do not believe that the proposed rule will create a significant impact on a substantial number of small entities. The Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small entities. We do, however, request comment on whether there are small entities that we have not identified that may be affected in a significant way by this proposed rule.

3. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

[49] The SBA references that annual receipts means ''total income'' (or in the case of a sole proprietorship, ''gross income'') plus ''cost of goods sold'' as these terms are defined and reported on Internal Revenue Service tax return forms. *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Nothing in this proposed rule imposes substantial direct compliance costs on State and local governments, preempts State law or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the standards, implementation specifications, or certification criteria that we propose for adoption.

4. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately $136 million. This final rule will not impose an unfunded mandate on State, local, and tribal governments or on the private sector that will reach the threshold level.

The Office of Management and Budget reviewed this proposed rule.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, proposes to amend as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

2. Amend § 170.102 by adding in alphanumeric order the definitions ''2011 Edition EHR certification criteria,'' ''2014 Edition EHR certification criteria,'' and ''Base EHR'' and revising the definitions of ''Certified EHR Technology'' and ''Complete EHR'' to read as follows:

§ 170.102 Definitions.

* * * * *

2011 Edition EHR certification criteria means the certification criteria at §§ 170.302, 170.304, and 170.306.

2014 Edition EHR certification criteria means the certification criteria at § 170.314.

Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources;

(v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

(3) Meets the certification criteria adopted by the Secretary at: § 170.314(a)(1) through (8); (b)(1) and (2); (c)(1) and (2); (d)(1) through (8); and (e)(1).

* * * * *

Certified EHR Technology means:

(1) For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:

(i) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or

(ii) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

(2) For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:

(i) The capabilities required to meet the definition of a Base EHR; and

(ii) All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

Complete EHR means EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting.

* * * * *

3. Add § 170.202 to read as follows:

§ 170.202 Transport standards.

The Secretary adopts the following transport standards:

(a) *Directed exchange. (1) Standard.* Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).

(2) Standard. External Data Representation and Cross-Enterprise Document Media Interchange for Direct Messaging (incorporated by reference in § 170.299).

(3) Standard. Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 (incorporated by reference in § 170.299).

(b) [Reserved]

4. Add § 170.204 to read as follows:

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility. Standard.* Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance (incorporated by reference in § 170.299).

(b) *Reference source. Standard.* Health Level Seven Context-Aware Knowledge Retrieval (Infobutton), International Normative Edition 2010 (incorporated by reference in § 170.299).

(c) *Clinical quality measure data capture and export. Standard.* National Quality Forum (NQF) Quality Data Model, Version 2011 (incorporated by reference in § 170.299).

5. In § 170.205, republish the introductory text and add paragraphs (a)(3), (d)(3), (e)(3), and (g) through (k) to read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and

associated implementation specifications:

(a) * * *

(3) *Standard.* HL7 Implementation Guide for Clinical Document Architecture, Release 2.0 (Consolidated CDA) (US Realm), Draft, September 2011 (incorporated by reference in § 170.299).

* * * * *

(d) * * *

(3) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299).

Implementation specifications. PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1 (incorporated by reference in § 170.299).

(e) * * *

(3) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299).

Implementation specifications. HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.3 (incorporated by reference in § 170.299).

* * * * *

(g) *Electronic transmission of lab results to public health agencies. Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata (incorporated by reference in § 170.299).

(h) [Reserved]

(i) Cancer information. Standard. HL7 Clinical Document Architecture (CDA), Release 2 (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012 (incorporated by reference in § 170.299).

(j) Imaging. Digital Imaging and Communications in Medicine (DICOM) PS 3—2011.

(k) Electronic incorporation and transmission of lab results. Standard. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm) (incorporation by reference in § 170.299).

6. In § 170.207, republish the introductory text, revise paragraph (f), and add paragraphs (a)(3), (b)(3), and (g) through (m) to read as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) * * *

(3) *Standard.* International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release January 2012 (incorporated by reference in § 170.299).

(b) * * *

(3) *Standard.* The code set specified at 45 CFR 162.1002(c)(3).

* * * * *

(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' available at *http://www.whitehouse.gov/omb/fedreg_1997standards*).

(g) *Laboratory tests. Standard.* Logical Observation Identifiers Names and Codes (LOINC®) version 2.38 (incorporated by reference in § 170.299).

(h) *Medications. Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, February 6, 2012 Release (incorporated by reference in § 170.299).

(i) *Immunizations. Standard.* HL7 Standard Code Set CVX—Vaccines Administered, August 15, 2011 version (incorporated by reference in § 170.299).

(j) *Preferred language. Standard.* ISO 639–1:2002 (incorporated by reference in § 170.299).

(k) *Preliminary determination of cause of death. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(l) *Smoking status. Standard.* Smoking status types must include: Current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.

(m) *Encounter diagnoses. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

7. In § 170.210 republish the introductory text and add paragraphs (e), (f), and (g) to read as follows:

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

* * * * *

(e) *Record actions related to electronic health information, audit log status, and encryption of end-user devices.* (1) When EHR technology is used to create, change, access, or delete electronic health information, the following information must be recorded:

(i) The electronic health information affected by the action(s);

(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g);

(iii) The action(s) that occurred;

(iv) Patient identification; and

(v) User identification.

(2) When the audit log is enabled or disabled, the following must be recorded:

(i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and

(ii) User identification.

(3) As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:

(i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and

(ii) User identification.

(f) *Encryption and hashing of electronic health information.* Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2 (incorporated by reference in § 170.299).

(g) *Synchronized clocks.* The date and time recorded utilize a system clock that has been synchronized following Request for Comments (RFC) 1305 Network Time Protocol (NTP) v3 (incorporated by reference in § 170.299) or RFC 5905 NTPv4 (incorporated by reference in § 170.299).

8. In § 170.300, republish paragraphs (a) and (b), revise paragraph (c) and add paragraph (d) to read as follows:

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, the use of at least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification criteria or capabilities specified within a certification criterion that are designated as optional.

(d) In § 170.314, all certification criteria and all capabilities specified

within a certification criterion have general applicability (i.e., apply to both ambulatory and inpatient settings) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

(1) *''Inpatient setting only''* means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an inpatient setting.

(2) *''Ambulatory setting only''* means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an ambulatory setting.

9. Add § 170.314 to subpart C to read as follows:

§ 170.314 2014 Edition electronic health record certification criteria.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) Clinical.

(1) Computerized provider order entry. Enable a user to electronically record, change, and access the following order types, at a minimum:

(i) Medications;

(ii) Laboratory; and

(iii) Radiology/imaging.

(2) Drug-drug, drug-allergy interaction checks.

(i) Interventions. Before a medication order is placed during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user at the point of care of drug-drug and drug-allergy contraindications based on medication list and medication allergy list.

(ii) Adjustments.

(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(3) Demographics.

(i) Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(j) and whether a patient declines to specify a preferred language.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality in accordance with the standard specified in § 170.207(k).

(4) Vital signs, body mass index, and growth charts.

(i) Vital signs. Enable a user to electronically record and change, and access recordings of a patient's vital signs including, at a minimum, height/length, weight, and blood pressure.

(ii) Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) Optional—Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

(5) Problem list. Enable a user to electronically record, change, and access a patient's problem list for longitudinal care in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

(6) Medication list. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history for longitudinal care.

(7) Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history for longitudinal care.

(8) Clinical decision support.

(i) Evidence-based decision support interventions. Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) Demographics;

(E) Laboratory tests and values/results; and

(F) Vital signs.

(ii) Linked referential clinical decision support.

(A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).

(B) Enable a user to access the reference information specified in paragraph (a)(8)(ii)(A) of this section relevant to patient context based on the data elements included in each one or any combination of the following:

(*1*) Problem list;

(*2*) Medication list;

(*3*) Medication allergy list;

(*4*) Demographics;

(*5*) Laboratory tests and values/results; and

(*6*) Vital signs.

(iii) Configure clinical decision support.

(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by an identified set of users (e.g., system administrator) based on each one of the following:

(*1*) A user's role;

(*2*) Clinical setting; and

(*3*) Identified points in the clinical workflow.

(B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i) of this section, when a summary care record is incorporated pursuant to § 170.314(b)(1).

(iv) Automatically and electronically interact. Interventions selected and configured in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:

(A) Bibliographic citation (clinical research/guideline) including publication;

(B) Developer of the intervention (translation from clinical research/guideline);

(C) Funding source of intervention development technical implementation; and

(D) Release and, if applicable, revision date of the intervention.

(9) Electronic notes. Enable a user to electronically record, change, access, and search electronic notes.

(10) Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(11) Smoking status. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(l).

(12) Imaging. Electronically indicate to a user the availability of a patient's images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations.

(13) Family health history. Enable a user to electronically record, change,

and access a patient's family health history.

(14) Patient lists. Enable a user to electronically select, sort, access, and create lists of patients according to, at a minimum, the data elements included in:

(i) Problem list;

(ii) Medication list;

(iii) Demographics; and

(iv) Laboratory tests and values/results.

(15) Ambulatory setting only—patient reminders. Enable a user to electronically create a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

(i) Problem list;

(ii) Medication list;

(iii) Medication allergy list;

(iv) Demographics; and

(v) Laboratory tests and values/results.

(16) Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to:

(i) At a minimum, each one of the data elements included in the patient's: problem list; medication list; and laboratory tests and values/results; and

(ii) The standard specified at § 170.204(b)(1).

(17) Inpatient setting only—electronic medication administration record.

(i) In combination with an assistive technology that provides automated information on the ''rights'' specified in paragraphs (a)(17)(i)(A) through (D) of this section, enable a user to electronically verify the following before administering medication(s):

(A) *Right patient.* The patient to whom the medication is to be administered matches the medication to be administered.

(B) *Right medication.* The medication to be administered matches the medication ordered for the patient.

(C) *Right dose.* The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) *Right route.* The route of medication delivery matches the route specified in the medication order.

(ii) Right time. Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

(18) Inpatient setting only—advance directives. Enable a user to electronically record whether a patient has an advance directive.

(b) Care coordination.

(1) Transitions of care—incorporate summary care record. Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider's name and contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalizations; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider.

(2) Transitions of care—create and transmit summary care record.

(i) Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(A) Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

(B) Race and ethnicity. The standard specified in § 170.207(f);

(C) Preferred language. The standard specified in § 170.207(j);

(D) Smoking status. The standard specified in § 170.207(1);

(E) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(F) Encounter diagnoses. The standard specified in § 170.207(m);

(G) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(H) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(I) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

(J) Medications. At a minimum, the version of the standard specified in § 170.207(h); and

(K) Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalizations; discharge instructions; and reason(s) for hospitalization.

(ii) Transmit. Enable a user to electronically transmit the summary care record created in paragraph (b)(2)(i) of this section in accordance with:

(A) The standards specified in § 170.202(a)(1) and (2).

(B) Optional. The standard specified in § 170.202(a)(3).

(3) Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

(i) The standard specified in § 170.205(b)(2); and

(ii) At a minimum, the version of the standard specified in § 170.207(h).

(4) Clinical information reconciliation. Enable a user to electronically reconcile the data elements that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date.

(ii) Enable a user to merge and remove individual data elements.

(iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the list.

(5) Incorporate laboratory tests and values/results.

(i) Receive results.

(A) Ambulatory setting only.

(*1*) Electronically receive clinical laboratory tests and values/results in accordance with the standard (and applicable implementation specifications) specified in § 170.205(k) and, at a minimum, the version of the standard specified in § 170.207(g).

(*2*) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Incorporate tests and values/results. Electronically incorporate a laboratory test and value/result with a laboratory order or patient record.

(6) Inpatient setting only—transmission of electronic laboratory

tests and values/results to ambulatory providers. Enable a user to electronically create laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(k); and

(ii) At a minimum, the version of the standard specified in § 170.207(g).

(c) Clinical quality measures.

(1) *Clinical quality measures—capture and export.*

(i) Capture. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).

(ii) Export. Electronically export a data file that includes all of the data elements that are represented in the standard specified in § 170.204(c).

(2) Clinical quality measures—incorporate and calculate.

(i) Incorporate. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures that are included in the EHR technology.

(ii) Calculate. Electronically calculate each clinical quality measure that is included in the EHR technology.

(3) Clinical quality measures—reporting. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS.

(d) Privacy and security.

(1) *Authentication, access control, and authorization.*

(i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

(2) *Auditable events and tamper-resistance.*

(i) *Enabled by default.* The capability specified in paragraph (d)(2)(ii) of this section must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.

(ii) *Record actions.* Record actions related to electronic health information, audit log status and, as applicable, encryption of end-user devices in accordance with the standard specified in § 170.210(e).

(iii) *Audit log protection.* Actions recorded in accordance with paragraph (d)(2)(ii) must not be capable of being changed, overwritten, or deleted.

(iv) *Detection.* Detect the alteration of audit logs.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the elements specified in the standard at § 170.210(e).

(4) *Amendments.*

(i) Enable a user to electronically amend a patient's health record to:

(A) Replace existing information in a way that preserves the original information; and

(B) Append patient supplied information, in free text or scanned, directly to a patient's health record or by embedding an electronic link to the location of the content of the amendment.

(ii) Enable a user to electronically append a response to patient supplied information in a patient's health record.

(5) *Automatic log-off.* Terminate an electronic session after a predetermined time of inactivity.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *Encryption of data at rest.* Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) If EHR technology manages electronic health information on an end-user device and the electronic health information remains stored on the device after use of the EHR technology on that device has stopped, the electronic health information must be encrypted in accordance with the standard specified in § 170.210(a)(1). This capability must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.

(ii) Electronic health information managed by EHR technology never remains stored on end-user devices after use of the EHR technology on those devices has stopped.

(8) *Integrity.*

(i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Optional—accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(e) *Patient engagement.*

(1) *View, download, and transmit to 3rd party.*

(i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:

(A) *View.* Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:

(*1*) Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions.

(*2*) *Inpatient setting only.* Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient.

(B) *Download.* Electronically download:

(*1*) A file in human readable format that includes, at a minimum:

(*i*) *Ambulatory setting only.* All of the data elements specified in paragraph (e)(1)(i)(A)(*1*) of this section.

(*ii*) *Inpatient setting only.* All of the data elements specified in paragraphs (e)(1)(i)(A)(*1*) and (*2*) of this section.

(*2*) A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(*i*) Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

(*ii*) *Race and ethnicity.* The standard specified in § 170.207(f);

(*iii*) *Preferred language.* The standard specified in § 170.207(j);

(*iv*) *Smoking status.* The standard specified in § 170.207(l);

(*v*) *Problems.* At a minimum, the version of the standard specified in § 170.207(a)(3);

(*vi*) *Encounter diagnoses.* The standard specified in § 170.207(m);

(*vii*) *Procedures.* The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(*viii*) *Laboratory test(s).* At a minimum, the version of the standard specified in § 170.207(g);

(*ix*) *Laboratory value(s)/result(s).* The value(s)/results of the laboratory test(s) performed;

(*x*) *Medications.* At a minimum, the version of the standard specified in § 170.207(h); and

(*xi*) *Inpatient setting only.* The data elements specified in paragraph (e)(1)(i)(A)(*2*) of this section.

(*3*) Images formatted according to the standard adopted at § 170.205(j).

(C) *Transmit to third party.* Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(*2*) of this section and images available to download in paragraph (e)(1)(i)(B)(*3*) of this section in accordance with:

(*1*) The standard specified in § 170.202(a)(1); and

(*2*) The standard specified in § 170.202(a)(2).

(ii) *Patient accessible log.*

(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(*1*) The electronic health information affected by the action(s);

(*2*) The date and time each action occurs in accordance with the standard specified at § 170.210(g);

(*3*) The action(s) that occurred; and

(*4*) User identification.

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

(2) Ambulatory setting only—clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the following data elements: Provider's name and office contact information; date and location of visit; reason for visit; patient's name; gender; race; ethnicity; date of birth; preferred language; smoking status; vital signs and any updates; problem list and any updates; medication list and any updates; medication allergy list and any updates; immunizations and/or medications administered during the visit; procedures performed during the visit; laboratory tests and values/results, including any tests and value/results pending; clinical instructions; care plan, including goals and instructions; recommended patient decision aids (if applicable to the visit); future scheduled tests; future appointments; and referrals to other providers. If the clinical summary is provided electronically, it must be:

(i) Provided in human readable format; and

(ii) Provided in a summary care record formatted according to the standard adopted at § 170.205(a)(3) with the following data elements expressed, where applicable, according to the specified standard(s):

(A) *Race and ethnicity.* The standard specified in § 170.207(f);

(B) *Preferred language.* The standard specified in § 170.207(j);

(C) *Smoking status.* The standard specified in § 170.207(l);

(D) *Problems.* At a minimum, the version of the standard specified in § 170.207(a)(3);

(E) *Encounter diagnoses.* The standard specified in § 170.207(m);

(F) *Procedures.* The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(G) *Laboratory test(s).* At a minimum, the version of the standard specified in § 170.207(g);

(H) *Laboratory value(s)/result(s).* The value(s)/results of the laboratory test(s) performed; and

(I) *Medications.* At a minimum, the version of the standard specified in § 170.207(h).

(3) Ambulatory setting only—secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient and EHR technology are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(f) *Public health.*

(1) *Immunization information.* Enable a user to electronically record, change, and access immunization information.

(2) *Transmission to immunization registries.* Enable a user to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(3); and

(ii) At a minimum, the version of the standard specified in § 170.207(i).

(3) *Public health surveillance.* Enable a user to electronically record, change, and access syndrome-based public health surveillance information.

(4) *Transmission to public health agencies.* Enable a user to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) *Ambulatory setting only.*

(A) The standard specified in § 170.205(d)(2).

(B) *Optional.* The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(ii) *Inpatient setting only.* The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(5) *Inpatient setting only—reportable laboratory tests and values/results.* Enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results.

(6) *Inpatient setting only—transmission of reportable laboratory tests and values/results.* Enable a user to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (g).

(7) *Ambulatory setting only—cancer case information.* Enable a user to electronically record, change, and access cancer case information.

(8) *Ambulatory setting only—transmission to cancer registries.* Enable a user to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (g).

(g) *Utilization.*

(1) *Automated numerator recording.* For each meaningful use objective with a percentage-based measure, electronically record the numerator.

(2) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(3) *Non-percentage-based measure use report.*

(i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage based, electronically record the date and time in accordance with the standard specified at § 170.210(g) when the capability was enabled, disabled, and/or executed.

(ii) Enable a user to electronically create a report of the information

recorded as part of paragraph (g)(3)(i) of this section.

(4) *Safety-enhanced design.* User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(17); § 170.314(b)(3); and § 170.314(b)(4).

§§ 170.500 through 170.599 [Amended]

10. In subpart E, consisting of §§ 170.500 through 170.599, remove the phrases ''permanent certification program for HIT'' and ''permanent certification program'' and add in their place ''ONC HIT Certification Program'' wherever they may occur.

11. Amend § 170.502 by revising the definition of ''providing or provide an updated certification'' to read as follows:

§ 170.502 Definitions.

* * * * *

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

* * * * *

12. In § 170.523, republish the introductory text, add paragraph (f)(8), and revise paragraph (k)(1)(i) to read as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

* * * * *

(f) * * *

(8) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

* * * * *

(k) * * *

(1) * * *

(i) ''This [Complete EHR or EHR Module] is [specify Edition of EHR certification criteria] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services.''; and

* * * * *

13. In § 170.550, revise paragraph (e), redesignate paragraph (f) as paragraph (g), and add a new paragraph (f) to read as follows:

§ 170.550 EHR Module certification.

* * * * *

(e) *Privacy and security certification.* For certification to the 2011 Edition EHR certification criteria, EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) When certifying an EHR Module to the 2014 Edition EHR certification criteria, an ONC–ACB must certify the EHR Module in accordance with the certification criteria at:

(1) Section 170.314(g)(1) if the EHR Module has capabilities presented for certification that would support a meaningful use objective with a percentage-based measure;

(2) Section 170.314(g)(3) if the EHR Module has capabilities presented for certification that would support a meaningful use objective with a non-percentage-based measure; and

(3) Section 170.314(g)(4) if the EHR Module is presented for certification to one or more listed certification criteria in § 170.314(g)(4).

* * * * *

14. Revise § 170.555 to read as follows:

§ 170.555 Certification to newer versions of certain standards.

(a) ONC–ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part, unless the Secretary prohibits the use of a newer version for certification.

(b) *Applicability of a newer version of a minimum standard.* (1) ONC–ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of standards identified as minimum standards in subpart B of this part, unless and until the incorporation by reference of a standard is updated in the **Federal Register** with a newer version.

(2) A certified Complete EHR or certified EHR Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

Dated: February 21, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–4430 Filed 2–24–12; 4:15 pm]

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Part IV

Department of Energy

10 CFR Parts 429 and 430
Energy Conservation Program: Test Procedures for Residential Clothes Washers; Final Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[Docket No. EERE–2010–BT–TP–0021]

RIN 1904–AC08

Energy Conservation Program: Test Procedures for Residential Clothes Washers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) establishes new test procedures for residential clothes washers under the Energy Policy and Conservation Act. The new test procedures include provisions for measuring standby mode and off mode energy consumption, and update the provisions for measuring active mode energy and water consumption. This final rule also amends the certification, compliance, and enforcement requirements for residential clothes washers, amends provisions for calculating the estimated annual operating cost for clothes washers, eliminates an obsolete clothes washer test procedure, and amends certain provisions in the currently applicable test procedure.

DATES: This final rule is effective April 6, 2012. Manufacturers will be required to certify compliance using the appendix J2 test procedure beginning on the compliance date of any final rule establishing amended energy conservation standards that address standby and off mode power for residential clothes washers. Before that time, manufacturers may continue to certify compliance using the test procedure at appendix J1.

The incorporation by reference of certain publications listed in this rulemaking is approved by the Director of the Office of the Federal Register as of April 6, 2012.

ADDRESSES: The docket is available for review at *http://www.regulations.gov*, including **Federal Register** notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the regulations.gov index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure. A link to the docket Web page can be found at: *www.regulations.gov/#!docketDetail;D=EERE-2010-BT-TP-0021*. The *regulations.gov* Web page contains instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov*.

FOR FURTHER INFORMATION CONTACT:

Mr. Stephen L. Witkowski, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–7463. Email: *Stephen.Witkowski@ee.doe.gov*.

Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–7796. Email: *Elizabeth.Kohl@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: This final rule incorporates by reference into part 430 the following industry test standards:

(1) AATCC Test Method 79–2010, Absorbency of Textiles, Revised 2010.

(2) AATCC Test Method 118–2007, Oil Repellency: Hydrocarbon Resistance Test, Revised 2007.

(3) AATCC Test Method 135–2010, Dimensional Changes of Fabrics After Home Laundering, Revised 2010.

(4) IEC Standard 62301, Household Electrical Appliances—Measurement of Standby Power, Edition 2.0, 2011–01.

Copies of AATCC standards can be obtained from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, NC 27709, (919) 549–3526, or *www.aatcc.org*.

Copies of IEC standards can be obtained from the American National Standards Institute, 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or *http://webstore.ansi.org/*.

Table of Contents

I. Authority and Background

Title III of the Energy Policy and Conservation Act (42 U.S.C. 6291, *et seq.;* ''EPCA'') sets forth a variety of provisions designed to improve energy efficiency. (All references to EPCA refer to the statute as amended through the Energy Independence and Security Act of 2007 (EISA 2007), Public Law 110–140 (Dec. 19, 2007)). Part B of title III, which for editorial reasons was redesignated as Part A upon incorporation into the U.S. Code (42 U.S.C. 6291–6309), establishes the ''Energy Conservation Program for Consumer Products Other Than Automobiles.'' These include residential clothes washers, the subject of this final rule. (42 U.S.C. 6292(a)(7))

Under EPCA, this program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. The testing requirements consist of test procedures that manufacturers of covered products must use as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA, and for making representations about the efficiency of those products. Similarly, DOE must use these test requirements to determine whether the products comply with any relevant standards promulgated under EPCA.

A. General Test Procedure Rulemaking Process

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA provides that any test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) If DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2))

DOE is codifying these changes to the clothes washer test procedure as a new appendix J2 in 10 CFR part 430 subpart B. Manufacturers will not be required to use appendix J2 to demonstrate compliance with clothes washer energy conservation standards until the compliance date of amended energy conservation standards that consider the methods and measurements included in the new test procedure. Until that time, manufacturers may continue to use appendix J1.

EPCA requires DOE to review its test procedures at least once every seven years to determine whether amendments are warranted. (42 U.S.C. 6293(b)(1)) This rulemaking satisfies EPCA's periodic review requirement. Table I.1 provides a summary of prior key regulatory and legislative actions regarding the residential clothes washer test procedure and energy conservation standards, which are relevant to this final rule. The first column contains the abbreviated names used in this preamble to refer to each action.

TABLE I.1—SUMMARY OF RELEVANT REGULATORY AND LEGISLATIVE ACTIONS FOR RESIDENTIAL CLOTHES WASHERS

Name	Action	Citation and date	Summary of action
TEST PROCEDURES			
August 1997 Final Rule	Final Rule	62 FR 45484 (August 27, 1997).	Established new test procedure at appendix J1.
September 2010 NOPR	Notice of Proposed Rulemaking.	75 FR 57556 (September 21, 2010).	Proposed new appendix J2 to incorporate standby and off mode and to amend certain active mode provisions; proposed changes to appendix J1; proposed removal of appendix J.
October 2010 public meeting.	Public meeting	October 28, 2010	Public meeting to discuss proposed test procedure amendments.
August 2011 SNOPR	Supplementary Notice of Proposed Rulemaking.	76 FR 49238 (August 9, 2011).	Proposed revisions to new appendix J2 to incorporate provisions of IEC Standard 62301 (2nd Ed.); proposed minor amendments to appendix J1.

TABLE I.1—SUMMARY OF RELEVANT REGULATORY AND LEGISLATIVE ACTIONS FOR RESIDENTIAL CLOTHES WASHERS—Continued

Name	Action	Citation and date	Summary of action
November 2011 SNOPR	Supplementary Notice of Proposed Rulemaking.	76 FR 69870 (November 9, 2011).	Proposed amended definition of the energy test cycle for the proposed new appendix J2.
ENERGY CONSERVATION STANDARDS			
January 2001 standards Final Rule.	Final Rule	66 FR 3314 (January 12, 2001).	Required use of appendix J1 to demonstrate compliance with amended energy conservation standards as of January 1, 2004; amended test procedure provisions related to remaining moisture content and test cloth.
August 2009 standards framework document.	Framework document	74 FR 44306 (August 28, 2009).	Developed to consider amended energy conservation standards.
September 2009 standards public meeting.	Public meeting	September 21, 2009	Public meeting to discuss energy conservation standards rulemaking; included test procedure issues.
LEGISLATION			
EPCA	Legislation	Energy Policy and Conservation Act, Pub. L. 94–163.	Established authority for energy conservation standards and test procedures.
EISA 2007	Legislation	Energy Independence and Security Act of 2007, Pub. L. 110–140.	Required standby and off mode energy to be integrated into overall energy descriptors for residential clothes washers, if technically feasible.

B. DOE Test Procedure at Appendix J1

The DOE test procedure for clothes washers currently being manufactured is found at 10 CFR part 430, subpart B, appendix J1, which was adopted by DOE in the August 1997 Final Rule. DOE added the new appendix J1 so that appendix J could still be used until DOE amended the residential clothes washer conservation standards [1], which DOE published in the January 2001 standards Final Rule. Until the compliance date of any amended standards for residential clothes washers, manufacturers may continue to use the appendix J1 test procedure to demonstrate compliance with current energy conservation standards.

The test procedure at appendix J1 includes provisions for determining the modified energy factor (MEF) and water factor (WF). The test procedure at appendix J1 does not address energy use in standby or off modes.

C. Clothes Washer Test Procedure Updates: Authority and Regulatory Background

EISA 2007 amended EPCA to require DOE to amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption into the overall energy efficiency, energy consumption, or other energy descriptor, unless the current test procedure already incorporates standby and off mode energy consumption, or if such integration is technically infeasible. If an integrated test procedure is technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure for the covered product, if a separate test is technically feasible. (42 U.S.C. 6295(gg)(2)(A)) Any such amendment must consider the most current versions of International Electrotechnical Commission (IEC) Standard 62301, ''Household electrical appliances—Measurement of standby power'' (''IEC Standard 62301 (Second Edition)'' or ''Second Edition'') and IEC Standard 62087, ''Methods of measurement for the power consumption of audio, video, and related equipment.'' [2] Amendments to test procedures to include standby and off mode energy consumption are not used to determine compliance with previously-established standards. (42 U.S.C. 6295(gg)(2)(C))

DOE is considering amending standards for clothes washers in a separate rulemaking, including amendments to the water consumption standards established in EISA 2007.[3] (42 U.S.C. 9295(g)(9) In the August 2009 standards framework document, available at *http://www1.eere.energy.gov/buildings/appliance_standards/residential/pdfs/clothes_washers_framework.pdf*, DOE requested comments on revising the clothes washer test procedure. Issues presented in the framework document, including issues related to the test procedure, were discussed at the September 2009 standards public meeting.

In response to the August 2009 standards framework document, DOE received comments stating that it should consider changes to the active mode test procedure for clothes washers. As a result, DOE proposed in the September 2010 NOPR to address issues regarding the active mode provisions of the test procedure, in addition to proposing the inclusion of measures for standby and off mode power. The proposals are discussed in greater detail below.

DOE proposed a number of revisions and additions to the test procedure in the September 2010 NOPR, including: (1) Incorporating standby and off mode power into a combined energy metric; (2) addressing technologies not covered by the appendix J1 test procedure, such as steam wash cycles and self-clean cycles; (3) revising the number of annual wash cycles; (4) updating use factors; (5) revising the procedures and specifications for test cloth; (6) redefining the appropriate water fill level for the capacity measurement method; (7) establishing a new measure of water consumption; and (8) revising the definition of the energy test cycle. DOE requested comment on the proposals in the September 2010 NOPR and discussed the proposals at the October 2010 public meeting.

[1] Because appendix J applies only to clothes washers manufactured before January 1, 2004, appendix J is now obsolete.

[2] IEC standards are available online at *www.iec.ch*.

[3] EISA 2007 amended EPCA, in relevant part, to revise the energy conservation standards for residential clothes washers. The revised standards established a maximum water consumption factor (WF) of 9.5, effective January 1, 2011.

The August 2011 SNOPR proposed to incorporate certain provisions of IEC Standard 62301 (Second Edition), as well as additional amendments addressing the following: (1) The energy test cycle definition; (2) the load adjustment factor; (3) the wash time setting for certain clothes washers; (4) the calculation of annual energy cost; (5) extension of the test load size table; (6) the definition of cold rinse; (7) redundant sections for test cloth specifications; (8) the detergent specification; (9) the definition of cold wash; and (10) the calculations for per-cycle self-clean water consumption. DOE requested comment on the proposals in the August 2011 SNOPR.

The November 2011 SNOPR proposed a revised definition for the energy test cycle. DOE requested additional comment on its proposal.

In today's final rule, DOE addresses comments it received on the September 2010 NOPR that were not previously addressed in the August 2011 SNOPR, as well as comments received in response to the August 2011 SNOPR and November 2011 SNOPR. DOE responds to these comments in section III.

II. Summary of the Final Rule

In this final rule, DOE establishes a new clothes washer test procedure (in a new appendix J2) that integrates measures of standby mode and off mode energy consumption, as well as measures of energy consumption in certain additional modes determined to be part of active mode. This final rule also: (1) Introduces a new efficiency metric for water consumption; (2) more accurately reflects current consumer usage patterns; (3) revises the energy test cycle definition; (4) revises the capacity measurement method; (5) addresses issues related to the test cloth, including the preconditioning detergent and test equipment; (6) clarifies certain testing conditions; (7) provides additional clarifications and corrections to certain provisions of the test procedure; (8) revises the calculation for annual operating cost; (9) revises and clarifies certain provisions in appendix J1; (10) removes the obsolete appendix J to subpart B of 10 CFR part 430; and (11) amends the certification, compliance, and enforcement requirements for residential clothes washers. The following paragraphs summarize these changes.

A. Standby and Off Mode

The new clothes washer test procedure includes provisions for measuring energy consumption in standby and off modes. DOE incorporates by reference IEC Standard 62301 (Second Edition). In the new test procedure, DOE includes language to clarify the application of clauses from the Second Edition regarding test conditions and test procedures for measuring standby mode and off mode energy consumption. The new test procedure includes definitions of ''active mode,'' ''standby mode,'' and ''off mode'' based on the definitions provided in the Second Edition. It also incorporates a simplified measurement approach that accounts for energy consumption in all low-power modes—including standby, off, delay start, and cycle finished modes—by means of a single power measurement. DOE also adopts a new measure of energy efficiency, the integrated modified energy factor (IMEF), which includes the energy used in the active, standby, and off modes.

B. Water Consumption

The new test procedure establishes a new measure of efficiency, the integrated water consumption factor (IWF), which incorporates the water consumption of all wash/rinse test cycles.

C. Updated Consumer Usage Patterns

The new test procedure updates certain values from the existing test procedure to reflect current consumer usage patterns and capabilities. This final rule: (1) Updates the number of annual wash cycles and incorporates it into the calculation for combined low-power mode energy consumption; (2) extends the test load sizes table to accommodate test loads for large-capacity clothes washers; (3) updates the temperature use factors for the warm/cold and warm/warm temperature combinations to accommodate the warm/warm cycle as a complete cycle; (4) updates the dryer usage factor; and (5) replaces the current representative load size calculation in the drying energy equation, which is based on the load adjustment factor, with a weighted-average load size based on the minimum, average, and maximum load sizes and the load usage factors.

D. Energy Test Cycle Definition

The new test procedure modifies the definition of the energy test cycle to improve clarity, which DOE believes will result in more accurate, repeatable, and reproducible results within and among all test laboratories.

E. Capacity Measurement Method

The new test procedure modifies the capacity measurement method to improve clarity, repeatability, and reproducibility, and to more appropriately represent the usable volume of the clothes washer during operation.

F. Test Cloth, Detergent, and Preconditioning Test Equipment

The new test procedure: (1) Includes new test cloth definitions; (2) establishes tolerances for the size and weight of the test cloth; (3) updates the detergent specification to reflect the current industry-standard detergent; (4) updates the test cloth preconditioning wash requirements; (5) updates the industry test methods referenced in the test procedure to reflect the current versions of each standard; (6) adds a new industry test method for measuring test cloth shrinkage; (7) adds a requirement to conduct extractor tests at the 650 g-force level; (8) updates the extractor specification; (9) adds specifications for the dryer to be used for bone-drying the test cloth; (10) clarifies the procedures for preparing and handling test cloth bundles; (11) clarifies the remaining moisture content (RMC) nomenclature used throughout the test procedure; (12) clarifies the application of the RMC correction curve; and (13) removes redundant sections regarding test cloth specifications and preconditioning, which were made obsolete by the January 2001 standards Final Rule.

G. Testing Conditions

Today's final rule clarifies the water supply pressure specification.

H. Clarifications and Corrections

This final rule: (1) Corrects the definition of ''cold rinse''; (2) clarifies the method for setting the wash time on clothes washers with electromechanical dials; (3) clarifies the definition of ''cold wash'' for clothes washers that offer multiple cold wash settings; (4) removes an obsolete note in the water factor calculation section; (5) corrects a typographical error in the equation for calculating per-cycle hot water consumption using gas-heated or oil-heated water; (6) removes the obsolete calculation of energy factor (EF); (7) clarifies the procedures recommended for conducting field tests in support of a test procedure waiver; (8) clarifies the water factor metric terminology; and (9) corrects typographical errors in materials incorporated by reference.

I. Annual Operating Cost Calculation

Today's final rule amends the annual operating cost calculation in 10 CFR 430.23(j) to incorporate the cost of energy consumed in standby and off

modes, and to reflect an updated number of annual use cycles.

J. Revisions to Appendix J1

This final rule revises and clarifies certain provisions in appendix J1, some of which are identical to revisions made in appendix J2. Manufacturers will continue to use the amended version of appendix J1 to certify compliance until use of appendix J2 is required for certification.

Specifically, this final rule: (1) Revises the introductory text to appendix J1; (2) corrects typographical errors in materials incorporated by reference; (3) corrects the definition of ''cold rinse''; (4) removes redundant sections regarding test cloth specifications and preconditioning, which were made obsolete by the January 2001 standards Final Rule; (5) updates the test cloth preconditioning detergent specification to reflect the current industry-standard detergent; (6) clarifies the method for setting the wash time for clothes washers with electromechanical dials; (7) clarifies the definition of ''cold wash'' for clothes washers that offer multiple cold wash settings; (8) removes an obsolete note in the water factor calculation section; (9) corrects a typographical error in the equation for calculating per-cycle hot water consumption using gas-heated or oil-heated water; (10) extends the load size table to accommodate test loads for large-capacity clothes washers; (11) clarifies the procedures recommended for conducting field tests in support of a test procedure waiver; and (12) corrects and clarifies provisions for calculating the RMC correction curve.

K. Removal of Appendix J

Today's final rule removes appendix J to subpart B of 10 CFR part 430, which became obsolete when appendix J1 became effective.

L. Certification, Compliance, and Enforcement Requirements

Today's final rule modifies the reporting requirements in 10 CFR 429.20(b)(2) by specifying that a certification report shall include publicly available information including MEF, WF, and capacity; as well the list of cycle settings comprising the complete energy test cycle for each basic model, which would not be made publicly available as part of the report. The requirement to provide the list of cycle settings comprising the complete energy test cycle will apply only to test results obtained using appendix J2.

III. Discussion

A. Products Covered by This Test Procedure Final Rule

Today's final rule covers residential clothes washers, defined as follows in 10 CFR 430.2:

Clothes washer means a consumer product designed to clean clothes, utilizing a water solution of soap and/or detergent and mechanical agitation or other movement, and must be one of the following classes: Automatic clothes washers, semi-automatic clothes washers, and other clothes washers.

Automatic clothes washer means a class of clothes washer which has a control system which is capable of scheduling a preselected combination of operations, such as regulation of water temperature, regulation of the water fill level, and performance of wash, rinse, drain, and spin functions without the need for user intervention subsequent to the initiation of machine operation. Some models may require user intervention to initiate these different segments of the cycle after the machine has begun operation, but they do not require the user to intervene to regulate the water temperature by adjusting the external water faucet valves.

Semi-automatic clothes washer means a class of clothes washer that is the same as an automatic clothes washer except that user intervention is required to regulate the water temperature by adjusting the external water faucet valves.

Other clothes washer means a class of clothes washer which is not an automatic or semi-automatic clothes washer.

Pursuant to 42 U.S.C. 6295(q), existing energy conservation standards divide residential clothes washers into five product classes (10 CFR 430.32(g)):

- Top-loading, Compact (less than 1.6 cubic feet capacity)
- Top-loading, Standard (1.6 cubic feet or greater capacity)
- Top-loading, Semiautomatic
- Front-loading
- Suds-saving

DOE received comments from interested parties regarding clothes washer product classes in response to the September 2010 NOPR. BSH Home Appliances (BSH) commented that it supports removing the distinction between front-loading and top-loading clothes washers. DOE notes that the amended test procedure contains provisions for testing both top-loading and front-loading clothes washers of varying capacities. DOE is considering the issue of how clothes washers should be grouped into product classes in the separate rulemaking addressing energy conservation standards for residential clothes washers (Docket EERE–2008–BT–STD–0019).

The People's Republic of China (China) commented that DOE did not specifically consider non-detergent types of clothes washers, and that DOE should set appropriate energy efficiency requirements for such non-detergent machines. (China, No. 19 at p. 4) DOE does not have any information on residential clothes washers currently available in the United States that use cleaning mechanisms other than the combination of water, detergent, and mechanical agitation. Therefore, DOE is not incorporating any changes to the definitions of covered products in today's final rule.

B. Standby Mode and Off Mode Test Procedure Provisions

This section describes the standby and off mode test procedure provisions adopted in today's final rule. DOE received a number of comments from interested parties regarding the standby and off mode definitions and test procedure provisions in IEC Standard 62301 proposed in the September 2010 NOPR. DOE responded to many of these comments in the August 2011 SNOPR and addresses additional comments from the September 2010 NOPR and the August 2011 SNOPR in the discussion that follows.

1. Version of IEC Standard 62301

DOE proposed in the September 2010 NOPR to incorporate by reference certain provisions from sections 4 and 5 of IEC Standard 62301 (First Edition), as well as certain provisions from the Committee Draft for Vote (CDV) version and the Final Draft International Standard (FDIS) version, developed prior to the issuance of the Second Edition. DOE received numerous comments in response to the September 2010 NOPR regarding the version of IEC Standard 62301, and provided responses to comments in the August 2011 SNOPR.

Based on comments from interested parties, DOE proposed in the August 2011 SNOPR to incorporate by reference the Second Edition of IEC Standard 62301 for measuring standby and off mode power. Specifically, DOE proposed referencing the following sections in the Second Edition: (1) The room ambient air conditions specified in section 4, paragraph 4.2; (2) the electrical supply voltage waveform specified in section 4, paragraph 4.3.2; (3) the power meter requirements specified in section 4, paragraph 4.4; (4) the note regarding the time required to

enter a stable power state in section 5, paragraph 5.1, note 1; (5) the installation instructions in section 5, paragraph 5.2; and (6) the power sampling method specified in section 5, paragraph 5.3.2.

DOE received the following comments in response to the August 2011 SNOPR: The Association of Home Appliance Manufacturers (AHAM), Alliance Laundry Systems (ALS), the Northwest Energy Efficiency Alliance (NEEA), and Whirlpool Corporation (Whirlpool) reiterated their support for incorporating by reference the Second Edition of IEC Standard 62301. AHAM and ALS stated that the Second Edition contains a number of important clarifications not present in the First Edition. Furthermore, AHAM and ALS stated that adopting the Second Edition will allow for international harmonization, which will give clarity and consistency to the regulated community. AHAM also stated that the Second Edition decreases testing burden. Whirlpool stated that the incorporation of the Second Edition should not be applicable until the effective date of appendix J2. (AHAM, No. 24 at p. 2; ALS, No. 22 at p. 1; NEEA, No. 26 at p. 2; Whirlpool, No. 27 at p. 1)

In this final rule, DOE incorporates by reference IEC Standard 62301 (Second Edition) for the test procedure in appendix J2. DOE believes that the new test procedures provide improved accuracy and representativeness of the resulting power measurement, and are not unduly burdensome to conduct, as described further in sections III.B.6 and III.G.1.

This final rule also amends 10 CFR 430.3 by adding a reference to IEC Standard 62301 (Second Edition). DOE retains the reference to the First Edition in 10 CFR 430.3 because several test procedures for other covered products not addressed in this final rule incorporate provisions from the First Edition.

Today's final rule also corrects the address and telephone number listed for the American National Standards Institute (ANSI) under the newly designated section for IEC standards in 10 CFR 430.3(m). The current address and phone number for ANSI is 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900. This correction is consistent with the address and phone number currently listed for ANSI in 10 CFR 430.3(c).

2. Determination of Modes To Be Incorporated

EPCA provides mode definitions for active mode, standby mode, and off mode, but authorizes DOE to amend these mode definitions by taking into consideration the most current version of IEC Standard 62301. (42 U.S.C. 6295(gg)(1)(B)) In the September 2010 NOPR, DOE noted that the mode definitions provided in IEC Standard 62301 (First Edition) and EPCA (as amended by EISA 2007) were designed to be broadly applicable for many energy-using products and could be subject to multiple interpretations. Therefore, DOE proposed mode definitions based on those provided in IEC Standard 62301 (FDIS), but with added clarifications specific to clothes washers.

In response to the September 2010 NOPR, NEEA commented that DOE's proposed modes and definitions would systematically exclude significant potential sources of annual energy use in many clothes washers. (NEEA, No. 12 at p. 2) NEEA also commented that DOE did not incorporate the ''Definitions'' section of IEC Standard 62301, and expressed concern about possible discrepancies between the modes specified in IEC Standard 62301 and the modes that are defined in EPCA. (NEEA, Public Meeting Transcript, No. 20 at pp. 22–23) NEEA added that not defining the modes identically with the IEC definitions could create inconsistencies in the way the modes are measured. (NEEA, Public Meeting Transcript, No. 20 at p. 24) NEEA's comments regarding specific modes and definitions are addressed in the relevant sections that follow.

For the reasons stated above, DOE maintained the mode definitions proposed in the September 2010 NOPR in the August 2011 SNOPR. DOE further proposed an ''alternate approach'' for measuring total energy consumption. In the alternate approach, the energy consumption of all low-power modes would be measured only in the inactive and off modes, and all low-power mode hours would be allocated to the inactive and off modes, depending on which of these modes is present.

In response to the August 2011 SNOPR, AHAM agreed that the Second Edition definitions are identical to those in the FDIS version and, thus, do not need to be revised. AHAM added that if DOE chooses to reference IEC Standard 62301 for those definitions, it should reference the Second Edition, not the FDIS, because the Second Edition is the final, published, and most current version of the standard. (AHAM, No. 24 at pp. 2–3)

DOE also proposed in the August 2011 SNOPR that certain installation instructions in IEC Standard 62301 (Second Edition) regarding the determination, classification, and testing of relevant modes were not appropriate for the clothes washer test procedure. Section 5, paragraph 5.2 of the Second Edition requires that where instructions for use provide configuration options, each relevant option should be separately tested. As stated in the August 2011 SNOPR, DOE is concerned that this requirement to separately test each configuration option could substantially increase test burden. It also potentially conflicts with the requirement in paragraph 5.2 to set up the product in accordance with the instructions for use or, if no such instructions are available, to use the factory or default settings. Accordingly, DOE proposed qualifying language in the test procedure amendments to disregard those portions of the installation instructions. For these reasons, DOE adopts language in today's final rule to disregard the provisions of paragraph 5.2 regarding the determination, classification, and testing of relevant modes.

The sections below provide additional details regarding the definition and inclusion of each specific mode within the revised test procedure.

Active Mode

DOE proposed in the September 2010 NOPR to define active mode as a mode in which the clothes washer is connected to a main power source; has been activated; and is performing one or more of the main functions of washing, soaking, tumbling, agitating, rinsing, and/or removing water from the clothing, or is involved in functions necessary for these main functions, such as admitting water into the washer or pumping water out of the washer. DOE also proposed including three additional modes within active mode: Delay start mode, cycle finished mode, and self-clean mode.

AHAM and the Pacific Gas and Electric Company (PG&E), Southern California Gas Company (SCG), San Diego Gas and Electric (SDG&E), and Southern California Edison (SCE) (collectively, the ''California Utilities'') support the active mode definition proposed in the September 2010 NOPR, which would include delay start, cycle finished, and self-clean modes. (AHAM, No. 14 at p. 4; California Utilities, No 18 at p. 2) However, AHAM stated that it opposes DOE's proposal to measure the energy use in delay start and cycle finished modes separately from the energy use of the active washing mode because delay start and cycle finished modes represent a very small contribution to the annual energy use. (AHAM, No. 14 at pp. 3–4) The California Utilities expressed concern

about how the power in these modes is measured and included in the proposed test procedure. (California Utilities, No 18 at p. 2)

NEEA agreed with the proposal to define delay start and cycle finished modes as active modes, but commented that the point at which the active washing mode ends and the inactive mode begins is not clear. NEEA recommended that DOE define the end of the active washing mode so that manufacturers will know when to stop the energy measurement. (NEEA, Public Meeting Transcript, No. 20 at p. 97; NEEA, No. 12 at pp. 2, 4, 5; NEEA, No. 26 at pp. 2, 4–5) NEEA further commented that the spin cycle is typically the last element of an active wash mode, and access to the clothes washing compartment is prevented until this part of the cycle has concluded; thus, the point at which the user can gain access to the wash compartment is one possible definition for the end of the active washing mode. (NEEA, No. 12 at p. 7; NEEA, No. 26 at p. 6)

NEEA also suggested that active mode could be defined as starting with the activation of the delayed start mode, if any (with the duration of delayed start mode specified), and ending with the beginning of the inactive mode (with the duration of the cycle finished mode, if any, specified, either in minutes or number of cycles or both). (NEEA, No. 12 at p. 4–5) NEEA expressed concern that the definition of the active washing mode leaves out functions that might occur in delay start, cycle finished, or self-clean modes. (NEEA, No. 12 at p. 4) NEEA further suggested that if delay start and cycle finished modes are defined as part of the active mode, DOE could include them in the definition of the active mode energy test cycle and specify their durations. NEEA noted that while this would lengthen the test cycle, it would probably result in an overall reduction in test procedure time by eliminating the setup time and separate measurement time required for measuring energy consumption in these two modes. (NEEA, No. 12 at p. 13–14)

The Natural Resources Defense Council (NRDC) questioned whether the active washing mode includes the pre- and post-parts of the active cycle. (NRDC, Public Meeting Transcript, No. 20 at pp. 96–97)

DOE notes that the adopted definition of active washing mode includes the main function of removing water from the clothing; *i.e.,* the final spin cycle, which is typically the last operation of a wash cycle. DOE infers from NEEA's comments that its concern about defining the end of active washing mode relates to clothes washers in which there may be additional energy-consuming functions other than a continuous status display in cycle finished mode, such as periodic tumbling or air circulation. As discussed in section III.B.2.c, this final rule does not require the testing of any cycle-finished activity. Thus, for the purpose of measuring energy consumption in the energy test cycle, the end of the active washing mode occurs at the end of the final spin to remove moisture.

This final rule also accounts for the energy use of delay start mode by allocating the hours not associated with active washing mode (which include those associated with delay start mode) to the inactive and off modes, as described in section III.B.7. The energy use of delay start mode is therefore not separately measured, as discussed in section III.B.2.b.

Delay Start Mode

In the September 2010 NOPR, DOE proposed to define delay start mode as an active mode in which the start of the active washing mode is facilitated by a timer. Because delay start mode is not a mode that may persist for an indefinite time, and is uniquely associated with the initiation of a main function (*i.e.,* washing cycle), DOE determined that it would not be considered as part of standby mode.[4] For this final rule, DOE has determined that because delay start is of limited duration and is uniquely associated with the initiation of a primary function, it should be considered part of active mode.

DOE proposed in the September 2010 NOPR to measure delay start mode by setting the delay start time to 5 hours, allowing at least a 5-minute stabilization period, and then measuring and recording the average power over a 60-minute measurement period.

In the August 2011 SNOPR, DOE proposed not to adopt provisions to measure delay start mode separately or as part of the active washing mode. Instead, DOE proposed adopting the ''alternate approach,'' in which all low-power mode hours would be allocated to the inactive and off modes, and the low-power mode energy consumption would be measured only in the inactive and off modes, depending on which of these modes is present.

ALS, AHAM, and Whirlpool supported DOE's proposal to consider delay start mode as part of active mode. (ALS, No. 10 at p. 1; AHAM, No. 14 at p. 3; Whirlpool No. 13 at p. 2) BSH supported the proposed delay start mode definition, and agreed that this mode should be included in the test procedure. (BSH, No. 17 at p. 2) AHAM and ALS supported using the ''alternate approach'' for measuring power in low-power modes. AHAM opposed separately measuring delay start mode, stating that the additional complexities of the test significantly add to the testing burden without a corresponding benefit to the public interest. AHAM stated that the *de minimus* amount of energy that will be measured, 0.04 to 0.2 kWh annually per DOE's data, will not add significantly, or possibly at all, to national consumption figures. (AHAM, No. 14 at p. 6; AHAM, No. 24 at p. 3; ALS, No. 22 at p. 2)

Whirlpool commented that the LED-based technology on which DOE proposed a 60-minute delay start mode is rapidly disappearing from new product introductions. (Whirlpool No. 13 at p. 3) Whirlpool also commented that the 60-minute delay start mode test would add substantial test burden (6–7 percent), with little or no impact on overall measured energy consumption. Whirlpool believes that this would create an unacceptable test burden for manufacturers and strongly urged the Department to drop this proposal. (Whirlpool No. 13 at p. 4)

NEEA agreed that delay start mode is an active mode, but stated that the measurement of energy consumption in this mode should be folded into the measurements during the active washing mode. (NEEA, No. 12 at p. 5; NEEA, No. 26 at pp. 2, 7) NEEA indicated that it would support the proposed methodology of setting a 5-hour delay and measuring for one hour if DOE continued with the proposal to measure the energy use of delay start mode separately. NEEA also stated that the warm-up period should be 10 minutes to be consistent with IEC Standard 62301 general procedures, rather than the proposed 5 minute warm-up period. (NEEA, No. 12 at p. 5) NEEA commented that DOE did not fully understand the reasons why delay start mode would be used in a

[4] DOE noted in the September 2010 NOPR that section 3.8 of IEC Standard 62301 Committee Draft 2 (IEC Standard 62301 CD2) provided the additional clarification that ''delay start mode is a one-off user-initiated short-duration function that is associated with an active mode.'' The subsequent IEC Standard 62301 CDV removed this clarification based on a comment from a committee member that the clarification conflicted with the proposed definition of ''standby mode,'' which would include ''activation of * * * active mode by * * * timer.'' In its response to that comment, however, the IEC reiterated that delay start mode is a one-off function of limited duration, even though it took action to delete the clarification in IEC Standard 62301 CDV. DOE inferred this to mean that that delay start mode should, therefore, be considered part of active mode. DOE also notes that Annex A of IEC Standard 62301 (Second Edition) classifies delay start as a secondary function and therefore not part of active mode.

household; according to NEEA, in some households the delayed start function is used to allow time for stain-removal compounds to work before the wash cycle starts. The delayed start time is based on the stain-removal compound manufacturer's recommendation for a soak time of 30 minutes. NEEA suggested that DOE acquire consumer data regarding usage of this feature, including the average time spent in delay start mode. (NEEA, No. 12 at pp. 5–6; NEEA, No. 26 at p. 7)

BSH commented that delay start mode contributes a negligible amount of energy consumption to consumers due to low usage and low energy consumption during usage. According to BSH, measuring this energy is not a valuable use of DOE or manufacturer lab resources. (BSH, No. 17 at p. 2) However, should measurement of delay start mode be required, BSH agrees with the proposed method. (BSH, No. 17 at p. 3)

Upon consideration of the data and estimates provided in the September 2010 NOPR, the uncertainty regarding consumer usage patterns, and the additional test burden that would be required, DOE has determined that measuring the energy consumption of delay start mode separately would introduce significant test burden without a corresponding improvement in a representative measure of annual energy consumption. Therefore, this final rule adopts the ''alternate approach,'' in which the energy use in all low-power modes (including delay start mode) is accounted for by allocating all low-power mode hours to the inactive and off modes. Low-power mode energy consumption is then measured in the inactive and off modes, depending on which of these modes is present. Section III.B.7 provides additional information regarding the measurement of low-power mode. As a result, this final rule does not include provisions to measure delay start mode separately as part of the active washing mode.

Cycle Finished Mode

DOE proposed in the September 2010 NOPR to define cycle finished mode as an active mode that provides continuous status display following operation in the active washing mode. As with delay start mode, cycle finished mode is not a mode that may persist for an indefinite time. Operation in cycle finished mode occurs only after operation in the active washing mode. Therefore, DOE considered cycle finished mode as a short-duration function associated with active mode and proposed to define cycle finished mode as a part of active mode.

DOE noted that some clothes washers available at the time of publication of the September 2010 NOPR offered energy-consuming features other than a continuous status display in cycle finished mode. For example, certain models may periodically tumble the clothes to prevent wrinkles for up to 10 hours after the completion of the wash cycle. Some models may also use a low-power fan to circulate air around the damp clothes to prevent odors. These functions, while enabled, would use more energy than the continuous display normally associated with cycle finished mode. However, DOE research indicated that the number of residential clothes washers equipped with such features represents less than 10 percent of the residential clothes washer market. In addition, review of product literature for the clothes washers equipped with such features shows that these features are typically consumer-selected options. DOE determined that measuring the energy use from these functions would significantly increase the test cycle duration to capture a negligible contributor to annual energy consumption. Therefore, DOE did not propose to amend the test procedure to address these specific cycle finished mode functions.

DOE received numerous comments in response to the September 2010 NOPR regarding cycle finished mode. ALS, Whirlpool, and AHAM stated that cycle finished mode should be considered a part of active mode. (ALS, No. 10 at p. 1; Whirlpool, No. 13 at p. 2; AHAM, No. 14 at p. 3) Whirlpool supported DOE's proposal to exclude cycle finished mode energy consumption due to air circulation or periodic tumbling because these functions are very limited in their application, and the measurement burden would substantially outweigh the value. (Whirlpool, No. 13 at p. 2) AHAM commented that it does not support measuring cycle finished mode separately from the rest of the active mode. (AHAM, No. 14 at p. 6)

NEEA disagreed with DOE's proposed cycle finished definition. NEEA commented that the proposed cycle finished mode definition comprises only a display function, which could exclude other energy-consuming features in a cycle finished mode. (NEEA, No. 12 at p. 2) Additionally, NEEA commented that it did not understand how DOE proposed to measure energy consumption in cycle finished mode for clothes washers with energy-consuming features other than a continuous status display, such as tumbling of the drum or a fan circulating air. (NEEA, Public Meeting Transcript, No. 20 at pp. 35–36) NEEA stated that, based on information from a clothes washer tax credit program conducted in the state of Oregon, it is aware of thousands of clothes washers that include tumbling after the end of the wash cycle. (NEEA, Public Meeting Transcript, No. 20 at p.37)

To address these concerns, NEEA proposed the following alternate definition of cycle finished mode: ''Cycle finished mode means the portion of the active mode between the end of the active washing mode and the beginning of the inactive mode.'' (NEEA, No. 12 at p. 2; NEEA, No. 26 at p. 4) NEEA also suggested that DOE create a methodology to measure cycle finished activity, which IEC Standard 62301 is attempting to do, so that any energy consumption that occurs during that period can be measured. (NEEA, Public Meeting Transcript, No. 20 at pp. 40–41) NEEA suggested that an appropriate temperature use factor (TUF) should be applied to delayed start and cycle finished modes. (NEEA, No. 31 at p. 2)

NRDC, the American Council for an Energy Efficient Economy (ACEEE), and the Appliance Standards Awareness Project (ASAP), jointly (hereafter, the ''Joint Commenters'') suggested that DOE expand the definition of cycle finished mode to include any energy-consuming features following operation in the active washing mode. The Joint Commenters stated that to avoid additional testing burden for clothes washers that only have a continuous display in cycle finished mode, DOE could specify a separate test procedure and a different number of annual hours to cycle finished mode for clothes washers with additional energy-consuming features. Additionally, this comment noted that if these features are not captured in the test procedure, manufacturers will have no incentive to reduce their energy consumption in cycle finished mode while providing the additional functionality. (Joint Commenters, No. 16 at p. 4) The Joint Commenters and the California Utilities also noted that machines having these additional features in cycle finished mode are likely to become more available in the marketplace in the future, and therefore it is not appropriate to exclude the energy consumption from these features in the test procedure. (Joint Commenters, No. 16 at pp. 3–4; California Utilities, No. 18 at p. 2)

BSH commented that DOE needs to define cycle finished mode more clearly. According to BSH, the proposed definition attempts to differentiate the

end-of-cycle signal from a ''left-on mode.'' BSH stated that it is unclear what is considered cycle finished mode and what is inactive mode, and that more clarity and detail is needed in the definition (BSH, No. 17 at p. 2)

In the August 2011 SNOPR, DOE presented results from additional laboratory testing to quantify the energy consumption in cycle finished mode. The test results indicated that including specific measurement of a cycle finished feature that incorporates intermittent tumbling and air circulation would not significantly impact the total annual energy consumption. Furthermore, measuring the energy use over the entire duration of the cycle finished mode could increase the test duration by up to 10 hours, depending on the maximum duration of the cycle finished mode provided on the clothes washer. Therefore, DOE proposed not to adopt provisions to measure cycle finished mode separately as part of the active washing mode.

In response to the August 2011 SNOPR, Whirlpool agreed with DOE's proposal not to adopt measurement of cycle finished mode, stating that the test burden would be substantially greater with virtually no consumer benefit. (Whirlpool, No. 27 at pp. 1–2)

NEEA disagreed with the definition of cycle finished mode and reiterated its proposal to define cycle finished mode as follows: ''Cycle finished mode means the portion of active mode between the end of the active washing mode and the beginning of the inactive mode.'' NEEA opposed ignoring cycle finished mode hours and energy use, and stated that the energy associated with cycle finished mode should be included as part of active mode. NEEA stated that in the worst case scenario, the energy use in cycle finished mode consumes around 20 percent of the total clothes washer machine energy, when dryer energy use is excluded. NEEA stated that cutting the cycle finished energy to one-third of the worst-case scenario would still represent 7 percent of the total machine energy consumption. NEEA stated that if energy use in cycle finished mode is considered to be insignificant, the same logic could be applied to standby and off modes, which is an argument Congress already rejected. (NEEA, No. 26 at pp. 2–7)

The Joint Commenters stated that the demonstrated potential consumption of energy in cycle finished mode warrants the testing of cycle finished mode in the test procedure. The Joint Commenters further stated that the amount of energy consumed in cycle finished mode is considerable when dryer energy is disregarded. The Joint Commenters stated that when dryer energy use is disregarded, inclusion of cycle finished mode doubles the amount of energy consumed while in low-power mode, causing the energy consumption to approach the energy consumed in active mode. The Joint Commenters believe that future clothes washers will likely incorporate more features in cycle finished mode, causing the energy consumption in that mode to increase to a more significant portion of the total per-cycle energy. The Joint Commenters support folding cycle finished mode into the existing active mode test cycle by either letting the clothes washer run through the completed cycle finished mode, or, alternatively, by terminating the test one hour after the clothes washer enters cycle finished mode. The Joint Commenters do not believe that this would significantly increase the test burden, as it would lengthen the test by one hour and would not require additional setup or test preparation. Finally, the Joint Commenters commented that the uncertainty of consumer usage patterns is an invalid argument against its inclusion in the test procedure, and that substituting reasonable estimates as proxies would suffice. (Joint Commenters, No. 23 at pp. 2–4)

The California Utilities suggested requiring separate measurements for cycle finished mode. The California Utilities stated that while they recognize that cycle finished mode represents a small percentage of energy consumption when compared to dryer energy, they believe it is a significant amount of energy and similar in magnitude to the electrical energy of the washer cycle. The California Utilities further commented in response to November 2011 SNOPR that they do not agree with DOE's assertion that cycle finished mode is activated only by the consumer, and that they possess knowledge that cycle finished mode is the default setting for certain clothes washer models, and cannot be deactivated or turned off. In addition, the California Utilities stated that there are other units that tumble more frequently than the model DOE tested. Furthermore, the California Utilities commented that the test procedure should measure all low-power modes, and that measuring all energy-consuming modes will encourage manufacturers to take efficiency into account at the beginning of their research and development efforts. (California Utilities, No. 25 at p. 2; California Utilities, No. 36 at pp. 1–2)

Upon consideration of the features that may be energized during the time period after the active washing mode and before the clothes washer enters inactive or off mode, DOE agrees that the proposed definition does not fully describe the possible functions in cycle finished mode. DOE concludes that periodic tumbling of the clothing or air circulation by means of a fan or blower constitute additional active mode functions outside the active washing mode, and thus should be included in the definition of cycle finished mode. Therefore, today's final rule adopts an expanded definition of cycle finished mode as ''an active mode that provides continuous status display, intermittent tumbling, or air circulation following operation in active washing mode.''

However, upon consideration of the data and estimates provided in the September 2010 NOPR, the additional energy consumption estimates provided in the August 2011 SNOPR, the uncertainty regarding consumer usage patterns, and the additional test burden required, today's final rule adopts the ''alternate approach'' to account for the energy use in cycle finished mode. Under this approach, all low-power mode hours are allocated to the inactive and off modes, and the low-power mode power is then measured in the inactive and off modes, depending on which of these modes is present. Section III.B.7 provides additional information regarding the measurement of low-power mode. DOE does not include provisions to measure cycle finished mode separately as part of the active washing mode.

Self-Clean Mode

In the September 2010 NOPR, DOE proposed to define self-clean mode as an active clothes washer operating mode that is (a) Dedicated to cleaning, deodorizing, or sanitizing the clothes washer by eliminating sources of odor, bacteria, mold, and mildew; (b) recommended to be run intermittently by the manufacturer; and (c) separate from clothes washing cycles. DOE considered self-clean mode as a part of the active mode because it is a function necessary for the main functions associated with washing clothes. A clothes washer with excessive bacteria, mildew, or odor cannot wash clothes effectively.

NEEA supports DOE's proposal to include self-clean mode as a part of active mode, and to include energy and water consumption in this mode in the test procedure. (NEEA, No. 12 at pp. 5, 9; NEEA, No. 26 at pp. 5–6) However, NEEA suggests the following definition of self-clean mode to clarify the proposed version: ''Self-cleaning mode means an active clothes washer operating mode that is recommended by

the manufacturer to be run for the purpose of cleaning, deodorizing, or sanitizing the clothes washer by eliminating sources of odor, bacteria, mold and mildew.'' (NEEA, No. 12 at p. 5; NEEA, No. 26 at pp. 6) NEEA stated that the number of self-clean annual cycles should be based on the recommendations of the manufacturer because consumers are unlikely to use these cycles in a way that is different than recommended. NEEA also strongly recommended that whatever cycle is recommended by a manufacturer for a self-cleaning function should be the one measured as the self-cleaning cycle. (NEEA, No. 12 at p. 9) NEEA also urged DOE to acquire consumer usage data on how self-clean cycles are actually used. (NEEA, No. 12 at p. 9; NEEA, No. 26 at p. 8)

The Joint Commenters support the inclusion of self-clean mode in the test procedure. The Joint Commenters stated that the definition should not be limited to machines equipped with an explicitly designated self-clean cycle, because self-cleaning may be undertaken with an appropriate cleaning compound through the use of a standard cycle available for washing clothes. (Joint Commenters, No. 16 at p. 3; Joint Commenters, No. 23 at p. 5)

The Joint Commenters also recommended that a usage factor of 12 cycles per year should not be uniformly applied to all washers, but rather should be based on the level of usage recommended by the manufacturer, converted as necessary to the appropriate number of cycles per year for the test procedure. This would provide further encouragement for manufacturers to develop approaches to sanitizing and deodorizing issues that are less energy- and water-intensive than current practices. (Joint Commenters, No. 16 at p. 3; Joint Commenters, No. 23 at p. 5)

The California Utilities commented that the proposed definition is potentially too restrictive because manufacturers may recommend intermittent self-clean cycles on machines without a dedicated self-clean feature or control. The California Utilities also commented that the calculation of self-clean cycles per year should be based on manufacturer recommendations in the product literature, rather than on a fixed number of annual self-clean cycles for all clothes washers. The California Utilities suggested that for clothes washer models that meet the definition of self-clean, but for which the manufacturer does not recommend a specific usage frequency for the self-clean cycle, the test procedure should assume the default value of 12 self-clean cycles per year. (California Utilities, No. 18 at p. 3; California Utilities, No. 25 at p. 3)

NRDC expressed concern that if a manufacturer recommends a periodic sanitizing regimen on a machine with no hardware or software dedicated to self-cleaning, these cycles would not be captured by the proposed definition. NRDC also commented that self-clean mode should be based on the manufacturer's recommendation, and not on design features. (NRDC, Public Meeting Transcript, No. 20 at pp. 47–48, 79–80)

Whirlpool commented that DOE should not include self-clean cycles in the clothes washer test procedure. Whirlpool stated that including this mode for clothes washers with such functionality, while not including it for other machines, disadvantages machines that include a self-clean cycle. According to Whirlpool, some consumer publications and manufacturers recommend running periodic cleaning cycles with baking soda or vinegar, and there is no known data on the consumer use of such practice. (Whirlpool, No. 13 at p. 2) Whirlpool proprietary data indicates that actual consumer use of a self-clean cycle is substantially less than the 12 times per year that DOE proposed, and that this data supports exclusion of self-clean energy from the test procedure. (Whirlpool, No. 13 at p. 5–6) Whirlpool also commented that if the self-clean cycle is included at the frequency of use recommended by the manufacturer, this could lead to manufacturers suggesting less frequent use. (Whirlpool, No. 13 at p. 5–6) Whirlpool estimated that the inclusion of a self-clean cycle in the test procedure would add approximately 8 percent to the overall test burden, or 8 hours, and that the amount of energy and water used by the average Whirlpool clothes washer during such cycles per year would be less than 1 percent of annual energy consumption and 3 percent of annual water consumption. Whirlpool believes that the added test burden outweighs the added benefit of including self-clean cycles in the test procedure. (Whirlpool, No. 13 at pp. 2, 6) However, Whirlpool agreed that if self-clean mode were included in the test procedure, it would be a part of active mode. (Whirlpool, No. 13 at p. 2).

AHAM opposes the inclusion of self-clean mode in the test procedure, but stated that if DOE decides to include it, AHAM agrees with the proposed definition as the best way to ensure measurement of all machines with a self-clean feature. (AHAM, No. 14 at p. 4) AHAM also notes that self-clean cycles have become necessary in large part due to the increasingly stringent energy and water consumption standards which, in practice, require many machines to use cold water instead of hot or warm water, and to use less water. (AHAM, No. 14 at p. 10) AHAM commented that there is no consumer use data to show whether and/or how often consumers use self-clean cycles, and that test procedures must be representative of actual consumer use, not manufacturer recommendations. AHAM believes that DOE should not include additional energy measurements in the test procedure without consumer data to support its addition and to quantify the energy impact. (AHAM, No .14 at p. 10) AHAM also commented that DOE's proposal to include self-clean cycles unfairly disadvantages clothes washers with a self-clean feature, which may dis-incentivize the feature, the result of which would not benefit consumers. AHAM stated that it is difficult to define an approach that would not encourage test procedure circumvention. (AHAM, No. 14 at p. 11).

BSH stated that self-clean mode should include only cycles specifically designed and provided for such activities. According to BSH, consumers are less likely to perform such activities without a dedicated program or option. (BSH, No 17 at p. 2) BSH commented that should the self-clean cycle be included, the number of cycles per year should be specified to match the manufacturer's suggestion to the customer. Otherwise, the motivation to reduce the need for such cycles is not present and manufacturers may not pursue innovations to reduce this need. (BSH, No. 17 at p. 2) However, BSH commented that it does not see the value to the consumer or DOE in assessing self-clean mode energy consumption, and suggests that these hours be removed or allocated to the active washing mode according to the self-cleaning cycles per year specified by the manufacturer. (BSH, No. 17 at p. 3) BSH stated that including the self-cleaning cycles will not significantly contribute to the annual energy consumption of residential washing machines. BSH suggests that instead of testing the self-clean cycle, the total number of annual active-mode cycles per year in the current energy calculations could be increased by a small value. (BSH, No. 17 at p. 2) Additionally, BSH does not agree that self-clean modes are necessary for the main functions associated with clothes washing, otherwise all clothes washers

would need such cycles. (BSH, No. 17 at p. 2).

ALS opposes DOE's proposed definition of self-clean mode as being part of active mode, and commented that DOE should not propose an energy test measurement without consumer use data to support it. (ALS, No. 10 at p. 1) ALS stated that self-clean cycles should not be added to the test procedure until there is reliable consumer data and an understanding of the energy consumed in self-clean cycles. ALS also stated that the test burden on manufacturers outweighs the public benefit at this time. (ALS, No. 10 at p. 3).

China does not support DOE's proposal to include self-clean mode in the test procedure. China commented that self-clean functions reduce bacteria and mildew that may harm the user, and thus are significant for health reasons. China stated that if self-clean mode were included in the test procedure, manufacturers might reduce the temperature or shorten the cycle time of a self-clean cycle to improve energy performance, which would be detrimental to consumers. China also expressed concern that this standard would lead to differences in energy consumption between units with and without self-cleaning functions, and stated that such distinct types of clothes washers should not be subject to the same energy standard. China noted that, as DOE proposed, self-clean mode represents a very short use time of only 16 hours per year, or 1.3 hours per month. Because of this minimal use time, China recommends not including the energy and water consumption during a self-clean cycle in the test procedure. (China, No. 19 at p. 3).

GE commented that it does not disagree with DOE's assumption of 12 self-clean cycles per year, but stated that consumers would be dissatisfied to have to use this feature monthly. GE expects that manufacturers will be working to reduce the required number of self-clean cycles per year. GE suggested that DOE use the manufacturer's recommendation for the number of self-clean cycles. (GE, Public Meeting Transcript, No. 20 at pp. 77–78, 107).

In reviewing these comments, DOE recognizes a lack of consensus regarding whether a self-clean mode is uniquely associated with a dedicated feature provided on a clothes washer, or whether self-clean mode may describe a consumer-initiated function associated with a normal wash cycle. DOE recognizes that a cleaning or deodorizing action in the clothes container may be achieved in either case, but that it is not clear whether such a cycle would be differentiable from a normal wash cycle in the event that a self-clean feature is not provided. In addition, DOE lacks information on the consumer usage of self-clean features or typical cycles run solely for self-clean purposes, including whether consumer usage reflects manufacturer recommendations. In light of this uncertainty, and considering that the annual energy use associated with self-clean mode would be relatively small, DOE has determined for today's final rule that self-clean mode should not be addressed in the amended test procedure. Therefore, DOE is not adopting a definition for a self-clean cycle, and is not adding any provisions to the test procedure for measuring self-clean energy and water consumption. In addition, today's final rule adds a clarifying statement that the energy test cycle shall not include any cycle, if available, that is dedicated for cleaning, deodorizing, or sanitizing the clothes washer, and is separate from clothes washing cycles.

Standby Mode

In the September 2010 NOPR, DOE proposed to define standby mode as any mode in which the clothes washer is connected to a main power source and offers one or more of the following user-oriented or protective functions, which may persist for an indefinite time: (a) To facilitate the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer; (b) continuous functions, including information or status displays (including clocks) and sensor-based functions.

DOE proposed an additional clarification that a timer should be considered a continuous clock function (which may be associated with a display) that provides regular scheduled tasks (*e.g.,* switching) and that operates on a continuous basis. This proposed definition was developed based on the definition provided in IEC Standard 62301 FDIS.

As proposed, the definition of standby mode allowed for multiple modes to be considered a standby mode. DOE had identified only one mode that would be considered a standby mode under the proposed definition. DOE proposed to define ''inactive mode'' as a standby mode that facilitates the activation of active mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display. Although it identified only this one particular standby mode, DOE remained open to consideration of additional standby modes. DOE retained this definition of standby mode in the August 2011 SNOPR.

ALS supported DOE's proposal for inactive mode to be the only standby mode. ALS also stated that it is unaware of any modes for clothes washers that represent significant energy use, other than those proposed by DOE. (ALS, No. 10 at p. 1) AHAM commented that it does not support the inclusion of one-way remote control energy in the definition of standby mode. According to AHAM, standard remote controls power down products rather than powering them off, such that the product can be turned on again through use of the remote. AHAM contrasted that to one-way remote controls, which turn a product off completely, such that it cannot be turned on again through use of the remote control. AHAM stated that one-way remote controls should be included under the definition of off mode to encourage manufacturers to design products with this feature, which could result in decreased energy use. (AHAM, No. 14 at p. 5).

Whirlpool stated that the test burden for inactive mode testing is significant (approximately an 8 percent increase) with virtually no consumer benefit. (Whirlpool, No. 13 at p. 4).

DOE notes that the definition of standby mode proposed in the September 2010 NOPR states that standby mode includes user-oriented or protective functions to facilitate the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer. If the clothes washer is consuming energy to power an infrared sensor used to receive signals from a remote control (while not operating in the active mode), such a function would be considered part of standby mode, regardless of whether the remote is classified as ''one-way'' or ''two-way.'' However, if a ''one-way'' remote control powers down the clothes washer, including turning off any infrared sensors to receive signals from a remote control, the unit would transition to off mode once it is powered down, if no other standby mode functions within the clothes washer are energized. Depending on whether the unit is capable of operating in both a standby mode and off mode or just the off mode, the annual hours associated with standby and off modes would be allocated accordingly.

In today's final rule, DOE retains the definitions of standby mode and inactive mode as proposed in the September 2010 NOPR and August 2011 SNOPR. Section III.B.7 provides further details on the test method for standby

mode adopted in the revised test procedure. As described further in section III.G.1, DOE believes that by adopting the ''alternate approach'' for measuring standby and off mode power, this final rule will not impose significant additional test burden on manufacturers.

Off Mode

DOE proposed in the September 2010 NOPR to define ''off mode'' as any mode in which the clothes washer is connected to a mains power source and is not providing any standby mode or active mode function, and the mode may persist for an indefinite time. An indicator that only shows the user that the product is in the off position would be included within the proposed off mode classification. This definition was developed based on the definitions provided in IEC Standard 62301 FDIS. DOE retained this definition of off mode in the August 2011 SNOPR.

Under the definitions proposed in the September 2010 NOPR, a clothes washer equipped with a mechanical on/off switch that can disconnect power to the display and/or control components would be considered as operating in the off mode when the switch is in the ''off'' position, provided that no other standby or active mode functions are energized. An energized light-emitting diode (LED) or other indicator that shows the user only that the product is in the off position would be considered part of off mode under the proposed definition, provided that no other standby or active mode functions are energized.

Other than those comments addressed in the August 2011 SNOPR, DOE did not receive any additional comments on the proposed definition of off mode. Therefore, for the reasons stated above and in the August 2011 SNOPR, DOE adopts this definition for the amended clothes washer test procedure in this final rule.

Network Mode

DOE noted in the September 2010 NOPR that IEC Standard 62301 FDIS provides definitions for network mode that DOE determined were not applicable to the clothes washer test procedure. Section 3.7 of IEC Standard 62301 FDIS defines network mode as a mode category that includes ''any product modes where the energy using product is connected to a mains power source and at least one network function is activated (such as reactivation via network command or network integrity communication) but where the primary function is not active.'' IEC Standard 62301 FDIS also provided a note, stating that ''[w]here a network function is provided, but is not active and/or not connected to a network, then this mode is not applicable. A network function could become active intermittently according to a fixed schedule or in response to a network requirement. A 'network' in this context includes communication between two or more separate independently powered devices or products. A network does not include one or more controls which are dedicated to a single product. Network mode may include one or more standby functions.'' DOE did not propose any amendments to include provisions for testing network mode energy consumption in clothes washers.

AHAM, ALS, BSH, and Whirlpool stated that network mode should not be included in the test procedure at this time because no products are currently available on the market with such a feature. (AHAM, No. 14 at pp. 5, 11; ALS, No. 10 at p. 3; BSH, No. 17 at pp. 3–4; Whirlpool, No. 13 at p. 2) Whirlpool, AHAM, and NRDC further commented that DOE could consider network mode by creating a ''placeholder'' for it in the test procedure, so that when there is sufficient volume of network-capable clothes washers in the market, this mode could be addressed. (Whirlpool, Public Meeting Transcript, No. 20 at pp. 42–43, 46; AHAM, Public Meeting Transcript, No. 20 at pp. 43–44, 109; NRDC, Public Meeting Transcript, No. 20 at pp. 109–110).

NEEA disagreed with DOE's proposal to not include provisions for network mode in the test procedure. NEEA stated that, although no clothes washers currently on the market are capable of this mode, it has communicated with microprocessor manufacturers who intend to sell the hardware that would allow such a mode. According to NEEA, informal estimates in these conversations revealed that network mode could significantly increase the energy consumption in the inactive mode. NEEA suggested that DOE define and allow for measuring the energy use of network mode, as defined in IEC Standard 62301, and recommended that DOE include network mode under the inactive mode definition. (NEEA, No. 12 at pp. 2, 4, 10; NEEA Public Meeting Transcript, No. 20 at pp. 38–41, 45–46; NEEA, No. 26 at p. 4) NEEA supports including the definitions and methodology for network mode energy from IEC Standard 62301 (Second Edition). NEEA also commented that if DOE chooses to incorporate a network mode definition different from that in IEC Standard 62301, there could be inconsistencies when the test method from IEC Standard 62301 is applied using DOE's mode definitions. (NEEA, Public Meeting Transcript, No. 20 at pp. 22–24; NEEA, No. 26 at p. 9).

The Joint Commenters stated that clothes washers with a network mode may become common by 2015 when the new standards take effect, and multiple manufacturers have indicated their plans to introduce these features. Therefore, the Joint Commenters believe it is important for the test procedure to capture at a minimum the standby energy consumption associated with a network mode. The Joint Commenters further stated that network mode could require power consumption of 2–5 Watts, corresponding to 18–44 kWh per year. According to the Joint Commenters, if network mode is not captured by the test procedures, manufacturers will have no incentive to employ lower-power technologies for this feature. (Joint Commenters, No. 16 at pp. 1–2) The Joint Commenters and the California Utilities stated that, due to the lack of sufficient data associated with development of a test method for network mode, DOE should develop a sufficiently broad definition for inactive or standby mode to ensure that the standby test method would capture any energy consumption associated with network functionality, regardless of whether the product is connected to a network. (Joint Commenters, No. 16 at p. 2; California Utilities, No. 18 at pp. 1–2; California Utilities, No. 25 at p. 2).

NRDC commented that the AHAM–ACEEE Agreement on Minimum Federal Efficiency Standards, Smart Appliances, Federal Incentives and Related Matters for Specified Appliances [5] includes an explicit commitment to recognize network functionality for major appliances in the ENERGY STAR context, so the test procedure should be prepared to assess whatever energy consumption is associated with that functionality. (NRDC, Public Meeting Transcript, No. 20 at pp. 41–42) The California Utilities further commented that DOE should include the definition of network mode to harmonize with the IEC Standard, and that it should act swiftly to issue an amendment to include a test method for network mode when it becomes aware of clothes washer models with this feature in the marketplace. The California Utilities expect network mode to become a regular feature in the future. The California Utilities stated that if DOE cannot develop a test procedure in this

[5] The AHAM–ACEEE Agreement on Minimum Federal Efficiency Standards, Smart Appliances, Federal Incentives and Related Matters for Specified Appliances is available at DOE Docket No. EERE–2010–BT–TP–0021, Comment No. 2.

rulemaking for products connected to networks, DOE should amend the test procedure as soon as it becomes aware of commercially available clothes washer models with this feature. (California Utilities, No. 18 at pp. 1–2; California Utilities, No. 25 at pp. 1–2).

DOE interprets the network mode provisions in IEC Standard 62301 (Second Edition) to be a forward-thinking attempt by the IEC to anticipate and/or promote technological change by industry. DOE is unaware, however, of any clothes washers currently on the market with network mode capabilities as of the date of today's final rule. Consequently, DOE can not thoroughly evaluate these network mode provisions, as would be required to justify their incorporation into DOE's test procedures at this time. DOE notes that although an individual appliance may consume some small amount of power in network mode, the potential exists for energy-related benefits that more than offset this additional power consumption if the appliance can be controlled by the ''smart grid'' to consume power during non-peak periods. Although DOE is supportive of efforts to develop smart-grid and other network-enabled technologies in clothes washers, today's final rule does not incorporate the network mode provisions due to the lack of available data that would be required to justify their inclusion.

Disconnected Mode

DOE noted in the September 2010 NOPR that section 3.9 of IEC Standard 62301 FDIS provided a definition of ''disconnected mode,'' which is ''the state where all connections to mains power sources of the energy using product are removed or interrupted.'' IEC Standard 62301 FDIS also added a note that common terms such as ''unplugged'' or ''cut off from mains'' also describe this mode, and that this mode is not part of the low-power mode category. Since there would be no energy use in a disconnected mode, DOE did not propose a definition or testing methods for such a mode.

AHAM agreed with DOE's proposal to not include test procedures for disconnected mode, because there would be no energy use in this mode. (AHAM, No. 14 at p. 5).

For the reasons stated in the September 2010 NOPR, DOE is not adopting a definition or testing methods for disconnected mode in this final rule.

3. Power Stabilization Criteria and Measurement Methods

In the September 2010 NOPR, DOE proposed to require measurement of standby mode and off mode power using section 5, paragraph 5.3 of the First Edition, clarified by requiring the product to stabilize for at least 30 minutes, and using a measurement period of not less than 10 minutes for cycle finished mode, inactive mode, and off mode. For instances where the power varies over a cycle, as described in section 5, paragraph 5.3.2 of the First Edition, DOE proposed to require the use of the average power approach in section 5, paragraph 5.3.2(a).

The Second Edition contains more detailed techniques for evaluating the stability of the power and measuring the power consumption of loads with different stability characteristics. In the Second Edition, the user is given a choice of measurement procedures, including a sampling method, average reading method, and direct meter reading method. In the August 2011 SNOPR, DOE evaluated these new methods in terms of test burden and improvement in results as compared to the methods provided in the First Edition. Based on this analysis, DOE proposed using the sampling method for all measurements of standby mode and off mode power. The following sections provide additional details on each power stability scenario.

Stable, Non-Cyclic Power

In the September 2010 NOPR, DOE proposed measuring stable, non-cyclic power by allowing the product to stabilize for at least 30 minutes, followed by a measurement period of at least 10 minutes using the test procedure specified in section 5, paragraph 5.3.1 of the First Edition. This method defines stable power as varying less than 5 percent over a 5 minute period. If the load is considered stable, the power can be recorded directly from the power-measuring instrument at the end of the measurement period.

In the August 2011 SNOPR, DOE proposed measuring stable, non-cyclic power by allowing the product sufficient time to reach its low power state and then following the test procedure for the sampling method specified in section 5, paragraph 5.3.2 of the Second Edition. The sampling method requires measuring and recording the power over a period of at least 15 minutes. Data from the first third of the measurement period are discarded, and stability is evaluated by a linear regression through all power readings in the second two-thirds of the data. If the slope of the linear regression satisfies the stability criterion, power consumption is calculated as the average of the power readings during the second two-thirds of the measurement period. If the slope of the linear regression does not satisfy the stability criterion, the total period is continuously extended—up to a maximum of 3 hours—until the stability criterion is satisfied for the second two-thirds of the data taken over the total period.

In response to the August 2011 SNOPR, NEEA supports DOE's proposal to require the use of the sampling method for measuring power consumption in the inactive and off modes. (NEEA, No. 26 at p. 2).

For the reasons stated in the August 2011 SNOPR, DOE specifies the use of the sampling method in section 5, paragraph 5.3.2 of the Second Edition for all measurements of standby and off mode power, including stable, non-cyclic power.

Unstable (Varying), Non-Cyclic Power

In the September 2010 NOPR, DOE proposed measuring unstable (varying), non-cyclic power by allowing the product to stabilize for at least 30 minutes, followed by a measurement period of at least 10 minutes using the average power approach described in section 5, paragraph 5.3.2(a) of the First Edition. The average power approach requires using an instrument that can measure the true average power over a period of at least 5 minutes (which DOE proposed to extend to a minimum of 10 minutes). The average power can be recorded directly from the power-measuring instrument at the end of the measurement period.

In the August 2011 SNOPR, DOE proposed measuring unstable (varying), non-cyclic power by allowing the product sufficient time to reach its low power state and then following the test procedure for the sampling method specified in section 5, paragraph 5.3.2 of the Second Edition. Using the sampling method, for modes that are known to be non-cyclic and unstable (varying), the test period must be long enough so that the cumulative average of all data points taken during the second two thirds of the total period fall within a band of ±0.2%.[6] When testing such modes, the total period must be at least 60 minutes.

For the reasons stated in the August 2011 SNOPR, DOE specifies the use of the sampling method in section 5, paragraph 5.3.2 of the Second Edition for all measurements of standby and off mode power, including unstable (varying), non-cyclic power.

[6] DOE interprets this provision as follows: The cumulative average is the mean of all data points up to and including the most recent data point. Each data point collected has a cumulative average associated with it, and the variation of those averages must remain within the given band.

Cyclic Power

In the September 2010 NOPR, DOE proposed measuring cyclic power by allowing the product to stabilize for at least 30 minutes, followed by a measurement period of at least 10 minutes using the average power approach described in section 5, paragraph 5.3.2(a) of the First Edition. The average power approach requires using an instrument that can measure the true average power over a period of at least 5 minutes (which DOE proposed to extend to a minimum of 10 minutes). The average power can be recorded directly from the power-measuring instrument at the end of the measurement period. For cyclic power, section 5.3.2(a) specifies that the test period shall be one or more complete cycles to get a representative average value.

In response to the September 2010 NOPR, NEEA commented that DOE should refer to the relevant sections of IEC Standard 62301 rather than try to simplify the language in section 3.11 of appendix J2, which could be potentially misleading or confusing. NEEA described a potential conflict between the language in DOE's proposed Section 3.11 of appendix J2 and that in the referenced IEC Standard 62301 test procedure: In the case of cycle finished mode, which often may involve more than just a display, cyclic power consumption may persist for a limited duration, which would require using the ''sampling approach'' for power measurement rather than the ''average power approach'' as proposed in section 3.11.2 of appendix J2. (NEEA, No. 12 at pp. 3–4) NEEA also stated that IEC Standard 62301 CDV specifications for a longer 30-minute stabilization period are superior to the shorter 10-minute period specified in the FDIS version. In addition, NEEA believes that if cyclic power changes are discovered during the stabilization period, the power measurement period should extend for at least four cycles or one hour, whichever is longer, noting that the sampling method in Section 5.3.1 of the IEC Standard 62301 FDIS calls for measurement over a minimum of four cycles in such circumstances. (NEEA, No.12 at p. 6).

In the August 2011 SNOPR, DOE proposed measuring cyclic power by allowing the product sufficient time to reach its low power state and then following the test procedure for the sampling method specified in section 5, paragraph 5.3.2 of the Second Edition. For cyclic power modes, the sampling method requires a measurement period of at least four complete cycles (for a total of at least 40 minutes), divided into two comparison periods. Stability is established by dividing the difference in average power measured in each comparison period by the time difference of the mid-point of each comparison period. This ''slope'' must satisfy the specified stability criterion. If the appropriate stability criterion is not satisfied, additional cycles are added to each comparison period until stability is achieved. Once stability has been achieved, the power is calculated as the average of all readings from both comparison periods.

As described in the August 2011 SNOPR, DOE believes that the methodology for measuring cyclic power in the Second Edition produces an improved measurement over the methodology from the First Edition.

DOE received no comments on this issue in response to the proposal in the August 2011 SNOPR. Therefore, for the reasons specified in the August 2011 SNOPR, DOE specifies the use of the sampling method in section 5, paragraph 5.3.2 of the Second Edition for all measurements of standby and off mode power, including cyclic power.

4. Use of Default Settings

In the September 2010 NOPR, DOE proposed that the clothes washer be installed according to the manufacturer's instructions, but did not propose additional provisions to require the use of default settings for testing standby energy consumption because it did not have information regarding the likelihood that consumers will alter the default display settings.

In the August 2011 SNOPR, DOE proposed incorporating by reference the installation instructions in section 5, paragraph 5.2 of the Second Edition. The Second Edition adds certain clarifications to the installation and setup procedures in section 5, paragraph 5.2 of the First Edition. The First Edition required that the product be installed in accordance with the manufacturer's instructions, except if those instructions conflict with the requirements of the standard, and that if no instructions are given, the factory or default settings must be used. The Second Edition adds provisions regarding products equipped with battery recharging circuits, as well as instructions for testing each relevant configuration option identified in the product's instructions for use. DOE is not aware of any clothes washers with a battery recharging circuit. DOE agreed with commenters that testing a clothes washer for standby mode energy use at the default setting, or as-shipped if a default setting is not indicated, would ensure consistency of results from test to test and among test laboratories.

NEEA supported DOE's proposal to disregard the portions of the installation instructions in section 5, paragraph 5.2 of IEC Standard 62301 that are not appropriate for the clothes washer test procedure; *i.e.,* those pertaining to batteries and the determination, classification, and testing of relevant modes. (NEEA, No. 26 at p. 2).

For the reasons stated in the August 2011 SNOPR, DOE adopts language in this final rule to disregard the provisions of paragraph 5.2 regarding batteries and, as described in section III.B.2, the provisions regarding the determination, classification, and testing of relevant modes. This final rule incorporates by reference, with qualification as discussed above, the installation instructions in section 5, paragraph 5.2 of the Second Edition.

5. Test Room Ambient Temperature Conditions for Standby Power Testing

DOE proposed in the September 2010 NOPR that test room ambient temperatures for standby mode and off mode testing be specified according to section 4, paragraph 4.2 of IEC Standard 62301 (First Edition). The current DOE test procedure includes a test room ambient air specification of 75 ± 5 °F, for water-heating clothes washers only. This specification is narrower than the range specified by IEC Standard 62301 of 73.4 ± 9 °F. The September 2010 NOPR proposal would require manufacturers of water-heating clothes washers to use the more stringent ambient temperature range in the current DOE test procedure if all active mode, standby mode, and off mode testing is conducted simultaneously in the same test room on multiple clothes washers. Alternatively, the temperature specifications in IEC Standard 62301 would allow a manufacturer that opts to conduct standby and off mode testing separately from active mode testing more latitude in maintaining ambient conditions. The test room ambient conditions specified in IEC Standard 62301 (Second Edition) are identical to those specified in the First Edition.

BSH and NEEA support DOE's proposals regarding test room ambient temperature range. (BSH, No. 17 at p. 3; NEEA, No. 12 at p. 6) AHAM, ALS, and Whirlpool support using 75 ± 5 °F as the test room ambient temperature. (AHAM, No. 14 at p. 7; ALS, No. 10 at p. 2; Whirlpool, No. 13 at p. 3) Whirlpool and AHAM believe that this requirement should apply to all clothes washer products, not just those that include water-heating capability, because ambient temperature

significantly impacts test procedure results and should be consistent across all machines. Whirlpool and AHAM stated that this tighter tolerance will help drive consistency, repeatability and reproducibility across machines and laboratories. (Whirlpool, No. 13 at p. 3; AHAM, No. 14 at p. 7; AHAM, Public Meeting Transcript, No. 20 at p. 58) AHAM commented further that should DOE proceed with its proposal for water-heating clothes washers only, it does not support allowing the use of the less stringent IEC range (73 ± 9 °F) because the more stringent DOE range (75 ± 5 °F) falls within the IEC range. Thus, there is no added test burden when the more stringent DOE range is used for testing standby and off modes. (AHAM, No. 14 at p. 7).

Whirlpool and AHAM commented that there appears to be some inconsistency between DOE's proposal and the proposed language from section 2.11.2 in appendix J2, as to whether DOE is proposing to allow use of the more stringent or less stringent ambient temperature range. It appears to Whirlpool and AHAM, based on the proposed language in section 2.11.2, that DOE's intent is to allow use of the less stringent IEC Standard 62301, First Edition ambient air temperature conditions of 73 ± 9 °F for measurement of standby, off, delay start, and cycle finished mode testing. (Whirlpool, No. 13 at p. 3; AHAM, No. 14 at p. 6) AHAM commented that DOE should reference IEC Standard 62301 Second Edition, FDIS version rather than the First Edition. (AHAM, No. 14 at p. 6).

After considering comments from interested parties, DOE has determined that the same ambient test room temperature requirement should apply to all clothes washer products, not just those that include water-heating capability. Because the temperature of the internal clothes washer components will be the same as the ambient room air temperature at the start of a test, maintaining the same ambient test room temperature would ensure that any heat loss from water in the machine during the test would be factored into the measured energy and water use in a consistent manner across all machines, both water-heating and non-water-heating. DOE also concurs with some commenters that the more stringent temperature range of 75 ± 5 °F will produce more accurate, repeatable, and reproducible results compared to the 73 ± 9 °F range. DOE also notes that the current test procedure requires a temperature range of 75 ± 5 °F for active mode testing. Therefore, performing standby and off mode testing at 75 ± 5 °F should not result in any additional test burden for manufacturers. For these reasons, today's final rule includes a test room ambient temperature specification of 75 ± 5 °F for both water-heating and non-water heating clothes washers. The amended test procedure does not adopt the test room ambient temperature range specified in IEC Standard 62031 (Second Edition) for standby and off mode testing.

6. Power Supply and Power Measuring Instruments

In the August 2011 SNOPR, DOE proposed to incorporate by reference the power supply and power-measuring instrument specifications in section 4, paragraphs 4.3 and 4.4 of the Second Edition. Specifically, paragraph 4.3.2 requires that the value of the harmonic content [7] of the voltage supply be recorded during the test and reported. Paragraph 4.4.1 requires the crest factor and maximum current ratio (MCR) to be determined. The value of MCR determines the maximum permitted uncertainty for the power measurement. Paragraph 4.4.3 requires the instrument to be capable of measuring the average power or integrated total energy consumption over any operator-selected time interval.

As described in the August 2011 SNOPR, DOE believes that the test burden associated with the additional measurements and calculations in the Second Edition is offset by the more reasonable requirements for testing equipment, while maintaining acceptable measurement accuracy. DOE also proposed in the August 2011 SNOPR for it to be acceptable to measure the total harmonic content, crest factor, and MCR before and after the actual test measurement if the power-measuring instrument is unable to perform these measurements during the actual test measurement.

AHAM, ALS, Whirlpool, and NEEA support DOE's proposed interpretation to allow measurement of the total harmonic content, crest factor, and maximum current ratio before and after the actual test measurement if the power-measuring instrument is unable to perform these measurements during the actual test measurement. (AHAM, No. 24 at p. 2; ALS, No. 22 at p. 1; NEEA, No. 26 at p. 2; Whirlpool, No. 27 at p. 1) Whirlpool added that individual manufacturers should decide whether to measure these parameters during the test, and that measuring the power parameters during the test would require some manufacturers to purchase new test equipment. Whirlpool believes that such economic burden should not be placed on manufacturers where an appropriate alternative exists. Whirlpool also commented that these test provisions should not be applicable until the effective date of appendix J2. (Whirlpool, No. 27 at p. 1).

DOE noted in the August 2011 SNOPR that performing the continuous linear regression analysis required by the sampling method in the Second Edition may require the use of data acquisition software with the capability of performing real-time data analysis. DOE requested comment on the potential test burden for a laboratory that would be required to upgrade its data acquisition system software to enable real-time data analysis capabilities.

AHAM stated that few laboratories currently have the real-time statistical analysis capabilities that DOE believed would be required to perform the continuous linear regression analysis of the stable, non-cyclic power test. AHAM added that several laboratories will need to invest both time and money to add a real-time statistical analysis capability to their data acquisition systems. AHAM further stated that updating data acquisition systems to enable real-time statistical analysis capabilities will require a significant upgrade. Whirlpool opposes the requirement to perform real-time statistical analysis because that such a requirement could require a significant capital investment by manufacturers. In addition, Whirlpool stated that the phrase ''real-time statistical analysis'' is vague and would require clarification if it were to be implemented. ALS stated that it has already equipped its lab to measure standby power per IEC Standard 62301 (First Edition) and understands that only a minimal software update expense would be needed to comply with the Second Edition. (AHAM, No. 24 at p. 2; ALS, No. 22 at p. 1; Whirlpool, No. 27 at p. 1).

After further testing and examination of the sampling method described in the Second Edition, DOE has determined that the analyses required by the sampling method could be performed without the need for real-time data analysis software. For example, a laboratory could acquire data for a discreet period of time and determine afterward whether the data satisfied the appropriate stability criteria. If these criteria were not satisfied, the laboratory could resume testing for a longer discrete period of time, followed by analysis of the data, and so on, until the

[7] As defined in the Second Edition, harmonic content (or total harmonic content) is equivalent to total harmonic distortion (on an amplitude, not power, basis; i.e., using the square root of the squares of the RMS voltages of the harmonics in the numerator).

stability criteria are satisfied. Therefore, a manufacturer or test laboratory could conduct standby and off mode testing using the sampling method in the Second Edition without being required to upgrade its software with real-time data analysis capabilities. DOE notes, however, that having such real-time data analysis capabilities would facilitate this testing.

In today's final rule, DOE specifies the use of the power supply and power-measuring instrument specifications in section 4, paragraphs 4.3.2 and 4.4 of the Second Edition. The amended test procedure also includes notes in section 2.2.2 (supply voltage waveform) and section 2.5.3 (power meter) stating that if the power-measuring instrument used for testing is unable to measure the total harmonic content, crest factor, power factor, or maximum current ratio during the measurement period, it is acceptable to measure and record these properties immediately before and after the test measurement period.

7. Calculation of Energy Consumption in Each Mode

In the September 2010 NOPR, DOE proposed two possible approaches for measuring energy consumption in modes other than active washing mode; *i.e.,* inactive (standby) mode, off mode, delay start mode, and cycle finished mode [8] (hereafter, collectively referred to as low-power modes). For the first approach, DOE proposed allocating 295 hours per year to the active washing mode, 16 hours to self-clean mode (if applicable), 25 hours per year to delay start mode (if applicable), 15 hours per year to cycle finished mode (if applicable), and the remainder to off and/or inactive mode. Using this approach, the energy use per cycle associated with inactive, off, delay start, and cycle finished modes would be calculated by (1) calculating the product of wattage and allocated hours for all possible inactive, off, delay start and cycle finished modes; (2) summing the results; (3) dividing the sum by 1,000 to convert from Wh to kWh; and (4) dividing by the proposed 295 use cycles per year. For clothes washers with electronic controls and a mechanical on/off switch, DOE proposed to allocate half of the inactive/off mode hours each to inactive and off modes.

For the second ''alternate approach,'' for the purpose of calculating the total energy consumed in all low-power modes, DOE proposed allocating all the hours not associated with active washing mode to the inactive and off modes and then measuring power consumption for the inactive and off modes. Using this approach, separate measurements of delay start and cycle finished mode energy consumption would not be required. This approach would allocate one hour to each active mode cycle, for a total of 295 active mode hours and 8,465 inactive/off mode hours. For clothes washers with electronic controls and a mechanical on/off switch, half of the inactive/off mode hours would be allocated each to inactive and off modes. DOE proposed using the alternate approach in the August 2011 SNOPR.

ALS commented that it supports DOE's proposal to allocate one hour to each active mode cycle. ALS also supports DOE's proposal to allocate half of the inactive/off hours each to inactive and off modes, for machines with electronic controls plus a mechanical on/off switch. (ALS, No. 10 at p. 2).

The Joint Commenters and ASAP support allocating a portion of the inactive/off hours to off mode for clothes washers with a mechanical on/off switch because of the potential energy-saving benefits that allow the consumer to reduce the energy consumption of the washer when not in use. The Joint Commenters and ASAP are concerned, however, about the lack of a specification regarding where the switch must be placed on the machine in order to receive credit. For example, a manufacturer could place a switch in a hidden location such as the back of the machine, where it would obviously not be intended for consumer use. (Joint Commenters, No. 16 at p. 4; ASAP, Public Meeting Transcript, No. 20 at p. 82) The Joint Commenters encourage DOE to specify that the switch must be placed on the front panel of the machine in order for half of the inactive/off mode hours to be allocated to off mode. (Joint Commenters, No. 16 at p. 4).

NEEA supports DOE's proposed alternate approach, with the caveat that delay start and cycle finished modes should be measured and included as part of the active wash mode. NEEA does not support DOE's proposal for using a one-hour average cycle time to determine annual active wash mode hours. NEEA stated that DOE's estimate, which was based on the behavior of a very limited sample of clothes washers, characterizes the behavior and energy use of the ''average'' clothes washer available in the market today, rather than measuring the actual performance of individual models. NEEA stated that the active washing mode hours should be based on the test results of the individual clothes washer model being tested. NEEA further commented that the energy use calculation could be greatly simplified if the calculation simply involved ''active mode'' and ''inactive mode hours,'' as measured for each model tested. Furthermore, NEEA does not support DOE's proposal to create a new class of modes called ''low-power modes,'' and stated that delay start and cycle finished modes should only be considered part of active mode and/or active washing mode. (NEEA, No. 12 at pp. 6–7; NEEA, No. 26 at pp. 2, 4, 6).

Whirlpool commented that it does not support DOE's proposal to split the non-active mode hours in half between inactive and off modes for washers with a mechanical or hard on/off switch. Whirlpool stated that such a device would add little benefit compared to its additional cost. Further, consumers are unlikely to utilize such a device unless it automatically defaults to the ''off'' mode at the end of each cycle (requiring the consumer to turn it to ''on'' for each new cycle initiated). According to Whirlpool, such an approach would be an annoyance to consumers and would cause consumers to postpone replacement purchases, thereby negating or delaying the resultant energy savings. Whirlpool stated that for any washer with a mechanical on/off switch, all of the non-active hours should be allocated to inactive mode. (Whirlpool, No. 13 at p. 4).

AHAM commented that it does not oppose using the estimate of one hour per cycle because it would be too burdensome and complicated to determine a more refined number, and there would be little corresponding benefit in accuracy. (AHAM, No. 14 at p. 7) AHAM also commented that it does not oppose DOE's proposal to allocate half of the inactive/off hours each to inactive and off modes for clothes washers with electronic controls plus a mechanical on/off switch. AHAM proposed that DOE add a requirement that the on/off switch must be accessible by the consumer, because a switch that is hidden such that the consumer might never find or use it should not be given this ''credit.'' AHAM further commented that this does not mean that DOE should specify product design by dictating where the switch should be placed on the machine. Furthermore, AHAM stated that there may be situations that warrant allocating all of the inactive/off hours to off mode; for example, there are machines that electronically turn off certain modes at the end of the active wash cycle and require the consumer to manually turn that mode back on to use it. (AHAM, No. 14 at p. 8).

[8] Self-clean mode, delay start mode, and cycle finished mode are considered part of the active mode.

DOE based its proposal to adopt an estimate of one hour per active mode wash cycle on the test data available. DOE concurs with AHAM's comment that performing additional testing to determine a more refined number would be too burdensome and complicated, with little corresponding benefit in overall accuracy. Basing the active washing mode hours on test results of the individual clothes washer model being tested would not be feasible because the energy test cycle includes numerous different wash cycles, each with a different cycle time. Calculating the average cycle time across all cycles for an individual washer would increase test burden with little or no corresponding increase in the accuracy of the results. Therefore, today's final rule allocates one hour to each active mode cycle, with 8,465 hours allocated to all other non-active mode cycles.

As described previously in section III.B.2, DOE adopts the ''alternate approach,'' in today's final rule, in which all low-power modes are allocated to the inactive and off modes, depending on which of these modes is present. The aggregate power of the low-power modes is represented by a single energy metric called ''combined low-power mode.'' DOE's analysis indicates that the assumption that the power in each low-power mode is similar, which DOE set forth in the September 2010 NOPR, remains valid, and that measuring the power of each mode separately would introduce significant test burden without a corresponding improvement in a representative measure of annual energy use.

Regarding the allocation of hours between inactive mode and off mode, the proposed definition of off mode as applied to residential clothes washers will primarily apply to units with mechanical controls. The proposed definition of inactive mode will primarily apply to units with electronic controls, in which reactivation of the clothes washer occurs through a pushbutton sensor, touch sensor, or other similar device that consumes power. DOE is not aware of any clothes washers on the market with electronic controls and an additional mechanical on/off switch. However, DOE believes that the test procedure should accommodate this option because of the potential energy-saving benefits provided by a mechanical on/off switch. DOE further notes that for units with all hours allocated to either inactive or off mode, the power measurement procedure and calculation of low-power mode energy consumption are identical. For these reasons, DOE adopts the proposal in the August 2011 SNOPR, which allocates 8,465 hours to off mode if no inactive mode is possible, 8,465 hours to inactive mode if no off mode is possible, and 4,232.5 hours to both inactive mode and off mode if both modes are possible.

DOE believes that manufacturers would be unlikely to install a mechanical on/off switch in an inaccessible location, because such a device would add little consumer benefit compared to its additional cost to the manufacturer. Therefore, today's final rule does address the location for an on/off switch.

8. Integrated Modified Energy Factor (IMEF)

The DOE test procedure for clothes washers currently provides a calculation for modified energy factor (MEF), which equals the clothes container capacity in cubic feet divided by the sum, expressed in kWh, of (1) the total weighted per-cycle hot water energy consumption, (2) the total weighted per-cycle machine electrical energy consumption, and (3) the per-cycle energy consumption for removing the remaining moisture from a test load. (See section 4.4 of appendix J1). The current Federal energy conservation standards for clothes washers are expressed in MEF. (10 CFR 430.32(g)(3))

As described previously in section I.C, EISA 2007 amended EPCA to require DOE to amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption into the overall energy efficiency, energy consumption, or other energy descriptor unless the current test procedure already incorporates standby and off mode energy consumption, or such integration is technically infeasible.

In the September 2010 NOPR, DOE proposed to establish an ''integrated modified energy factor'' (IMEF) for residential clothes washers. DOE proposed to calculate IMEF as the clothes container capacity in cubic feet divided by the sum, expressed in kWh, of:

- The total weighted per-cycle hot water energy consumption;
- The total weighted per-cycle machine electrical energy consumption;
- The per-cycle energy consumption for removing moisture from a test load;
- The per-cycle standby, off, delay start, and cycle finished mode energy consumption; and
- The per-cycle self-clean mode energy consumption, as applicable.

In the August 2011 SNOPR, DOE proposed not to allocate the hours for delay start and cycle finished modes to the inactive and off modes, and not require separate measurements for delay start and cycle finished mode energy consumption. Therefore, DOE modified the proposed IMEF calculation by incorporating per-cycle combined low-power mode energy consumption instead of separate measurements of per-cycle standby, off, delay start and cycle finished mode energy consumption.

NEEA and the California Utilities support the IMEF calculation proposed in the September 2010 NOPR. (NEEA, No. 12 at p. 8; California Utilities, No. 18 at p. 2) The California Utilities further commented that although the low-power modes represent a relatively small portion of annual energy and water use, they should be measured in the test procedure because these loads will become an increasingly significant portion of overall energy use as clothes washers and other appliances make efficiency gains in their primary active mode. (California Utilities, No. 18 at p. 2).

ALS opposes the IMEF calculation proposed in the September 2010 NOPR, which separates out per-cycle standby, off, delay start, and cycle finished mode energy consumption. ALS noted that there is little public benefit to including these modes, and that DOE has no reliable consumer use data on which to base the calculations. ALS stated there is no need for a new IMEF metric. (ALS, No. 10 at p. 2).

AHAM also objected to the new IMEF measure of energy consumption due to the significant time, resource, and cost impacts associated with it. AHAM also stated that the added test burden provides no corresponding public benefit. (AHAM, No. 14 at p. 8).

NRDC questioned DOE's decision to retain a metric based on a per-cycle measure rather than an annual metric, such as for dishwashers. (NRDC, Public Meeting Transcript, No. 20 at pp. 91–92).

DOE determined in the September 2010 NOPR that it is technically feasible to integrate standby mode and off mode energy consumption into the overall energy consumption metric for clothes washers, which for the current energy conservation standards is based on the per-cycle MEF.

The current test procedure does not provide an additional energy descriptor for annual energy consumption. Any new descriptor for annual energy consumption would be based on the same per-cycle energy use measurements from which MEF or IMEF is calculated, multiplied by the number of annual use cycles; therefore, an annual energy use metric incorporating standby and off mode energy use would

not be inherently more accurate or representative than MEF or IMEF. The analogous change from a per-cycle metric to annual energy use for the energy conservation standards for dishwashers was required by Congress in the provisions of EISA 2007.

As described in section III.B.2.d, this final rule does not adopt a definition for a self-clean cycle and is not adding any provisions to the test procedure for measuring the energy and water consumption of a self-clean cycle. Today's final rule also implements the alternate approach for measuring energy consumption in low-power modes. Therefore, today's final rule calculates IMEF as the clothes container capacity in cubic feet divided by the sum, expressed in kWh, of:

- The total weighted per-cycle hot water energy consumption;
- The total weighted per-cycle machine electrical energy consumption;
- The per-cycle energy consumption for removing moisture from a test load; and
- The per-cycle combined low-power mode energy consumption.

C. Active Mode Test Procedure Provisions

1. Integrated Water Consumption Factor (IWF)

The existing calculation of water factor (WF) in the appendix J1 test procedure accounts only for the water consumed during the cold wash/cold rinse cycle. Hot water consumption is measured for all wash cycles, including warm, hot, and extra-hot washes, but it is used only to determine the energy needed to heat the water. If the cold wash water consumption is set disproportionately low, while more water is used at higher temperatures, the WF metric may not accurately reflect the average water consumption of the machine.

In the September 2010 NOPR, DOE proposed a new water consumption metric, integrated water consumption factor (IWF). This proposed metric would account for both the hot and cold water consumption of each test cycle, including any steam or self-clean cycles. As proposed, IWF would equal the sum of the total weighted per-cycle water consumption for all wash cycles and the per-cycle self-clean water consumption, divided by the clothes container volume. As proposed, the total weighted per-cycle water consumption for all wash cycles would be calculated as the TUF-weighted sum of the total per-cycle water consumption for each test cycle.

In the August 2011 SNOPR, DOE proposed a correction to the calculation for per-cycle self-clean water consumption. The proposed calculations in the newly-proposed sections 4.1.8 (per-cycle self-clean hot water energy consumption) and 4.2.14 (total per-cycle self-clean water consumption) did not contain the numeric multipliers required to apportion the total annual self-clean water consumption over the 295 representative average number of clothes washer cycles in a year. The August 2011 SNOPR proposal adjusted the calculations in section 4.1.8 and 4.2.14 by including a multiplier of 12/295, where 12 represents the average number of clothes washer self-clean cycles in a year, and 295 represents the average number of clothes washer cycles in a year.

ALS, the Joint Commenters, and NEEA expressed support for the proposal to measure water consumption for all active mode energy test cycles as part of the IWF metric. NEEA also supported DOE's proposed use of TUFs and load usage factors to derive the active mode water consumption. (ALS, No. 10 at p. 4; Joint Commenters, No. 16 at p. 8; Joint Commenters, No. 23 at p. 5; NEEA, No. 12 at p. 13) AHAM, the California Utilities, and Whirlpool specifically stated support for the inclusion in an IWF metric of hot and cold water measurements from all cycles tested. AHAM and the Joint Commenters noted that those values are already measured as part of the test procedure, and thus would not add to test burden. NEEA similarly commented that the proposed methodology for IWF would not add significant new test burden on manufacturers. Whirlpool stated that the proposal to include all water usage would prevent manufacturers from varying the amount of rinse water used at different temperatures, and that this would justify any additional test burden. (AHAM, No. 14 at p. 15; California Utilities, No. 18 at p. 5; Joint Commenters, No. 16 at p. 8; NEEA, No. 12 at p. 13; Whirlpool, No. 13 at p. 13) BSH stated that if the standards are adjusted appropriately, cold water consumption from all tests can be used in calculations. (BSH, No. 17 at p. 4) NRDC agreed with the IWF in concept. (NRDC, Public Meeting Transcript, No. 20 at pp. 182–183) The California Utilities and NEEA support the inclusion of water use from self-clean cycles in the IWF measurement. (California Utilities, No. 18 at p. 5; NEEA, No. 12 at p. 13) The Joint Commenters stated that DOE's proposal would provide a more representative depiction of water consumption. (Joint Commenters, No. 16 at p. 8).

AHAM, ALS, and Whirlpool do not support including the water use in self-clean cycles in the IWF metric. AHAM agrees, however, with the proposed correction to adjust the calculation using a multiplier of 12/295, if DOE determines that self-clean cycles should be included in the energy and water calculations. ALS also opposes the inclusion of water use in steam cycles in IWF. ALS stated that until DOE has a reliable understanding of the consumer usage and water consumed in self-clean and steam cycles, it should not include these in the test procedure. (AHAM, No. 14 at p. 15; AHAM, No. 24 at p. 5; ALS, No. 10 at pp. 4–5; Whirlpool, No. 13 at p. 13) According to BSH, inclusion of self-clean and steam cycles in the test procedure would lead to minimal improvement in IWF but would increase the test burden. (BSH, No. 17 at p. 3).

As described in sections III.B.2.d, III.C.2.a and III.C.2.b, DOE did not adopt provisions for measuring the water and energy consumption of self-clean cycles or steam cycles. In today's final rule, DOE includes an integrated water factor (IWF) metric that is based on the total weighted per-cycle water consumption of both hot and cold water for all wash cycles comprising the energy test cycle. Because these values are already measured as part of the test procedure, and no new test equipment would be required to measure these values, manufacturer test burden would not increase. DOE believes that an IWF defined in this way provides a more representative measure of total water consumption for a clothes washer.

2. Technologies Not Covered by the Current Test Procedure

Steam Wash Cycles

DOE is aware of multiple clothes washer models currently available on the market offering steam functions via pre-set cycles, or as an optional addition to conventional wash cycles. During these cycles, steam is injected into the basket, which manufacturers claim provides enhanced cleaning and/or sterilization. The steam is produced in a generator that requires a significant amount of energy to heat and vaporize the water. The current clothes washer test procedure does not account for energy or water consumption during this type of wash cycle.

In the September 2010 NOPR, DOE proposed amending the test procedure to include additional measurement of energy and water consumption during a steam wash cycle for clothes washers offering this feature. In the proposed amendments, an additional set of steam cycle tests would be required for clothes washers that offer such a feature. The

test sections required for clothes washers without a steam wash cycle would remain unchanged.

DOE also proposed in the September 2010 NOPR to include the energy and water consumption from steam wash cycles in the final calculations for the energy and water use metrics. For clothes washers capable of steam wash cycles, the measurements of energy and water consumption from the steam wash cycle with the hottest wash temperature would be included in the overall energy and water use calculations, based on the TUF for steam wash. Table 4.1.1 (Temperature Use Factors) of appendix J1 specifies the current weighting factor applied to the consumption measurements for the different wash cycles. DOE proposed to update Table 4.1.1 to include 0.02 as the TUF of a steam wash cycle, when available. DOE assumed these cycles would decrease the use of extra-hot cycles, but would leave the use of hot, warm, and cold cycles unchanged. DOE believed that the steam wash cycles would be selected somewhat fewer times than the extra hot cycle because on some models steam is available as an option only on certain settings. DOE therefore estimated that the 0.02 TUF associated with steam washes would correspond to a 0.02 decrease in the TUFs associated with extra-hot cycles, for a steam-capable clothes washer.

The California Utilities, the Joint Commenters, and NEEA expressed qualified support for DOE's proposal to include the energy and water use of steam wash cycles in the test procedure, and raised concerns about the definition of ''steam wash cycle.'' The California Utilities and NEEA commented that DOE may need to refine the definition of steam wash cycle for clarity and consistency. The Joint Commenters stated that the definition of ''steam wash cycle'' should include not only the injection of ''steam'' (vaporized water) but also any superheated water injected in the form of mist or fine droplets. The Joint Commenters also stated that all energy and water use resulting from steam wash cycles should be accounted for, including any injections made after the conclusion of the final spin cycle. (California Utilities, No 18 at p. 3; Joint Commenters, No. 16 at p. 3; Joint Commenters, No. 23 at pp. 4–5; NEEA, No. 12 at p. 9; NEEA, No. 26 at pp. 7–8) NEEA suggested that DOE gather data on steam cycles to more clearly define what constitutes a steam cycle. (NEEA, No. 12 at p. 9; NEEA, No. 26 at p. 8).

AHAM, ALS, BSH, and Whirlpool oppose adding measures of the energy and water consumption of steam wash cycles to the clothes washer test procedure without sufficient data on consumer usage patterns of such cycles. (AHAM, No. 14 at p. 9; ALS, No. 10 at p. 3; BSH, No. 17 at p. 3; Whirlpool, No. 13 at p. 5) ALS, BSH, and Whirlpool also oppose the inclusion of steam wash cycles due to the added manufacturer test burden, particularly because the energy use in these cycles represents such a small amount of the total annual energy. Whirlpool commented that the test burden would increase by about 10 percent. (ALS, No. 10 at p. 3; BSH, No. 17 at p. 3; Whirlpool, No. 13 at p. 5) AHAM and Whirlpool also noted that DOE does not have data on the percentage of clothes washers on the market with a steam feature. Whirlpool estimates that this percentage is likely in the single digits. (AHAM, No. 14 at p. 9; Whirlpool, No. 13 at p. 5; Whirlpool, Public Meeting Transcript, No. 20 at pp. 102–103) BSH further opposes the inclusion of steam wash cycles in the energy and water test methods because the longevity of these features in the market has yet to be proven. (BSH, No. 17 at p. 3).

GE and LG also commented that DOE needs to clarify the definition of steam wash cycle. GE suggested modifying the definition of steam cycle as: ''Steam cycle means a wash cycle in which water is heated to the point of boiling to produce steam and in which that steam is injected into the clothes container.'' (GE, Public Meeting Transcript, No. 20 at p. 104; GE, No. 35 at p. 2; LG, Public Meeting Transcript, No. 20 at p. 103).

AHAM questioned whether a definition of steam wash cycle would include a required temperature to which water must be heated for steam to be generated in the cycle, a representative duration of time for which steam must be injected into the drum, and a definition of the term ''injected''. AHAM stated that it would be difficult to define ''steam wash cycle'' in a clear, repeatable, reproducible, and uniformly applicable way. According to AHAM, without a better definition of steam wash cycle, there will be confusion among manufacturers, which will lead to confusion in the market as consumers attempt to compare products. (AHAM, No. 14 at pp. 9–10) Springboard Engineering (Springboard) requested clarification as to whether steam would be tested at the hottest temperature available in the ''normal'' cycle, or whether it would be tested at the hottest temperature available on any cycle, such as a sanitize cycle. Springboard also noted that some clothes washers have cycles with wash temperatures greater than 135°F and steam, and stated that it is not clear how these cycles should be tested. (Springboard, No. 11 at pp. 2–3).

DOE also received comments in response to the proposed TUF for steam wash cycles. AHAM, ALS, NEEA, and Whirlpool do not support DOE's proposed steam wash cycle TUF. AHAM stated that because it does not support the inclusion of steam wash cycles in the DOE test procedure, it also opposes the revision of the TUFs to account for steam wash cycles. AHAM also questioned the assumption that the steam wash cycle TUF affects only the extra-hot TUF. (AHAM, No. 14 at p. 12) Similarly, NEEA questioned the basis on which DOE assumed that a steam wash cycle would mostly or always be associated with a hot wash cycle. According to NEEA, some consumers use a hot or extra-hot wash to kill dust mites and other allergens, not just for heavily soiled loads, and it is not clear whether such users would select a cooler wash cycle with a steam feature to accomplish the same thing. ALS, NEEA and Whirlpool objected to DOE's assignment of a TUF for steam wash cycles without supporting data. (ALS, No. 10 at p. 4; NEEA, No. 12 at p. 9; NEEA, No. 26 at p. 8; Whirlpool, No. 13 at pp. 5, 8) Whirlpool also stated that the usage of steam wash cycles is quite limited, since they are specialized cycles designed for removal of difficult stains. (Whirlpool, No. 13 at pp. 5, 8) Springboard questioned whether there are machines on the market that have a steam wash cycle but do not have a hot wash cycle. (Springboard, No. 11 at p. 3).

DOE notes that the implementation of ''steam cycles'' may vary among manufacturers, and that the proposed definition may lead to inconsistent interpretations of whether a certain feature constitutes a ''steam cycle'' to be included in the energy test cycle. In addition, consumer usage of steam features is likely to be low. For these reasons, DOE does not adopt provisions to measure the energy and water use in steam wash cycles, and therefore is not amending the TUFs in the clothes washer test procedure to include a TUF for steam wash cycles that would occur in place of certain extra-hot wash cycles.

Self-Clean Cycles

DOE is aware that some residential clothes washers currently on the market offer a self-clean cycle. These cycles are used periodically with bleach and/or detergent—but no clothes load—to clean, deodorize, or sanitize the components that come into contact with water by preventing or eliminating the formation of mold, bacteria, and

mildew. Self-clean cycles may require higher water temperatures and greater volumes of water than a normal cycle, and therefore could potentially consume a substantial amount of energy. The current test procedure does not account for energy or water consumption attributable to self-clean cycles.

As described previously in section III.B.2.d, DOE proposed in the September 2010 NOPR to define a ''self-clean mode'' as a clothes washer operating mode that:

- Is dedicated to cleaning, deodorizing, or sanitizing the clothes washer by eliminating sources of odor, bacteria, mold, and mildew;
- Is recommended to be run intermittently by the manufacturer; and
- Is separate from clothes washing cycles.

As described in the September 2010 NOPR, DOE observed that manufacturers typically recommended running a self-clean cycle once a month. Some manufacturers also recommend a self-clean cycle after a defined number of clothes washing cycles. Because these self-clean cycles are not accounted for in the proposed 295 wash cycles per year, DOE proposed to integrate the energy and water consumption of self-clean cycles into the overall energy efficiency metrics, under the assumption that these cycles are typically run once per month.

DOE received comments in response to the proposal to account for energy and water consumption of self-clean cycles in the overall calculations for IMEF and IWF, which are discussed in III.B.2.d, III.B.8, and III.C.1. For the reasons presented in those sections, DOE is not adopting provisions in today's final rule to include measures of self-clean energy and water use in the clothes washer test procedure.

Adaptive Control Technologies

Adaptive control technologies can adjust parameters such as agitation intensity, number of rinses, wash time, and wash and rinse temperatures based on the size, fabric mix, and soil level of a wash load. The current test procedure accounts for adaptive fill technologies, but no other types of adaptive controls.

DOE is aware that other consumer products employ adaptive controls, and that these are addressed in their respective test procedures. For example, many dishwashers incorporate adaptive controls by means of a turbidity sensor which adjusts the number and duration of wash and rinse cycles. The dishwasher test procedure accounts for these models through the use of soiled dishware loads. (10 CFR part 430, subpart B, appendix C).

In the September 2010 NOPR, DOE noted that it was not aware of any clothes washers available on the market that incorporate adaptive controls using a turbidity sensor. If clothes washers become available that offer adaptive controls using a turbidity sensor, DOE could consider amending the clothes washer test procedure to measure energy and water consumption with a soiled wash load. However, because it was not aware of any clothes washers incorporating this technology, DOE did not propose to address adaptive controls other than adaptive fill control in the test procedure.

AHAM, BSH, NEEA, and Whirlpool supported DOE's proposal that no adaptive control provisions other than the existing adaptive fill control methodology be adopted in the clothes washer test procedure at this time. (AHAM, No. 14 at p. 11; BSH, No. 17 at p. 4; NEEA, No. 12 at p. 9; NEEA, No. 26 at pp. 8–9; Whirlpool, No. 13 at p. 6) According to BSH and Whirlpool, there are currently no clothes washers on the market with soil-sensing technology. (BSH, No. 17 at p. 4; Whirlpool, No. 13 at p. 6) Whirlpool stated that if a soil-sensing clothes washer were to exist, it would require some form of sensor, which in turn would require a soiled test load to activate the sensor and properly record the energy used (analogous to the test procedure for soil-sensing dishwashers). According to Whirlpool, DOE would need to develop a uniform, consistent, repeatable, and reproducible soil load, which could take 3 or more years. (Whirlpool, No. 13 at p. 6) NEEA agreed that turbidity sensors for soil-sensing are unlikely to be found in clothes washers, but the increasing complexity of control capabilities should not be ignored. NEEA urged DOE to gather enough statistically valid data to inform a decision on whether to adopt provisions for measuring adaptive control technologies. NEEA further commented that, in the absence of information on clothes washer models with adaptive control technologies other than adaptive fill control, DOE should state how the presence of such technologies might affect the test procedure results. (NEEA, No. 12 at pp. 9–10; NEEA, No. 26 at pp. 8–9).

DOE observes that manufacturers representing approximately 65 percent of the U.S. clothes washer market stated that they are unaware of soil-sensing clothes washers currently available, supporting DOE's preliminary conclusion. For this reason, DOE is unable to evaluate any technical approaches towards adaptive control outside of adaptive fill control, nor can it develop appropriate methodology for evaluating the energy use of such features. Therefore, DOE is not adopting new provisions addressing adaptive control technologies in today's final rule.

Demand Response Technologies

Demand response technology enables an appliance to shift its activity based on interaction with the electric grid, utilities, or user programming. Appliances that can communicate with the electric grid or any other network would be considered to have a network mode as defined by IEC Standard 62301 Second Edition. As described previously in section III.B.2.g, the Second Edition defines network mode as a mode category that includes ''any product modes where the energy using product is connected to a mains power source and at least one network function is activated (such as reactivation via network command or network integrity communication) but where the primary function is not active.'' IEC Standard 62301 Second Edition also provides a note stating, ''[w]here a network function is provided but is not active and/or not connected to a network, then this mode is not applicable. A network function could become active intermittently according to a fixed schedule or in response to a network requirement. A 'network' in this context includes communication between two or more separate independently powered devices or products. A network does not include one or more controls which are dedicated to a single product. Network mode may include one or more standby functions.''

As discussed in section III.B.2.g, DOE did not propose in the September 2010 NOPR to amend the clothes washer test procedure to include any provisions for measuring energy consumption in network mode, because it was unaware of any clothes washers currently available on the market that incorporate a networking function. Additionally, DOE was unaware of any data regarding network mode in clothes washers that would enable it to determine appropriate testing procedures and mode definitions for incorporation into the test procedure.

AHAM commented that there is currently insufficient data regarding demand response features in clothes washers, but that when these features become available, DOE should address them in the test procedure. AHAM noted that it is currently working with energy and water efficiency advocates to develop a definition of ''smart appliances,'' including a definition of ''smart'' clothes washers. (AHAM, No. 14 at p. 11; AHAM, Public Meeting Transcript, No. 20 at p. 109) NEEA

doubted whether any significant fraction of laundry activities take place at peak hours, and thus it is skeptical whether households would shift their laundry schedules in response to time-of-use rates or a signal from a ''smart grid'' system. Even so, NEEA supported including provisions for network mode in the clothes washer test procedure for use when machines with such capabilities appear on the market. (NEEA, No. 12 at p. 10).

For the reasons stated in the September 2010 NOPR, this final rule does not incorporate provisions for clothes washers with demand response technologies. However, DOE is generally supportive of efforts to develop smart-grid and other network-enabled technologies in clothes washers. Provisions for testing power consumption in network mode could be incorporated into the test procedure through future amendments, once the appropriate data and testing methodologies become available.

3. Consumer Usage Patterns

In the September 2010 NOPR and August 2011 SNOPR, DOE proposed updating some of the consumer usage patterns contained in the test procedure. General comments on the proposals are discussed immediately below, and comments related to the specific consumer usage patterns for which DOE proposed changes are discussed in the sections that follow.

AHAM commented generally that DOE should gather or develop information on contemporary laundry practices in the United States for incorporation into the test procedure, including temperature settings, average cycles per year, special-purpose machine cycles (such as steam and self-clean), the size of a minimum laundry load, the size of an average load, and the frequency distribution of various laundry loads. (AHAM, No. 2 at p. 23; AHAM, No. 14 at pp. 1–2). EarthJustice and NRDC support this recommendation. (EarthJustice, No. 3 at p. 1; NRDC, No. 8 at p. 1) Whirlpool stated that a test procedure proposal would not be valid, meaningful, or representative of consumer practices without data to validate the underlying assumptions. Whirlpool requests that DOE accept input from manufacturers and/or initiate primary research efforts of its own to obtain updated consumer usage data, as necessary. (Whirlpool, No. 13 at p. 1).

NEEA commented that, because the revised test procedure will not be required for use before the effective date of any revised efficiency standards, DOE should take the time now to acquire enough statistically valid data to properly specify the usage patterns and calculations within the test procedure. (NEEA, No. 12 at pp. 1, 10, 16) NEEA added that DOE should consider more systematic efforts to gather field data in advance of the start of future rulemakings where test procedure changes are expected. (NEEA, No. 31 at p. 3) NEEA commented that it is currently gathering field data on the laundry habits from households participating in the Residential Building Stock Assessment, expected to be complete by mid-2013. By June 2012, field data on clothes washer and dryer energy use, the nature and size of laundry loads, washer and dryer cycle choices, and number of cycles per year will become available. (NEEA, No. 31 at p. 2).

NEEA also stated that it believes DOE is moving toward a test procedure that delivers performance results for an ''average'' product, rather than the specific clothes washer models being tested. NEEA believes that this approach would undermine the basic intent of the test procedure and the standards, which it believes should reasonably reflect energy and water use for each model. (NEEA, No. 12 at pp. 1–2).

DOE is aware of ongoing and future planned field studies by DOE and other parties, which are expected to provide relevant data regarding current consumer usage patterns. DOE will consider any relevant data resulting from these studies in future test procedure rulemakings.

Number of Annual Wash Cycles

In the January 2001 standards Final Rule, DOE estimated the representative number of annual wash cycles per clothes washer as 392. This number is not used in the calculations for the current energy efficiency metric, because MEF is calculated on a per-cycle basis. To include energy consumption from modes other than active washing mode in the energy efficiency metric requires an estimate of the time a typical clothes washer spends in active washing and all other non-active washing modes. The number of annual wash cycles is used to determine the time spent in the active washing mode, and also determines the remaining time to be allocated to the other possible modes.

In the September 2010 NOPR, DOE proposed 295 as the representative number of wash cycles per year, based on the 2005 Residential Energy Consumption Survey (RECS) data. DOE determined preliminarily that this was a more representative value than the results of the California Residential Appliance Saturation Survey (California RASS), which indicated 283 annual cycles, because the RECS survey was nationwide rather than limited to a single state. DOE also made a preliminary determination that the 2005 RECS value was more representative of average use than the value based on a Procter & Gamble (P&G) study, which indicated 308 annual cycles, due to the household size distributions of the data sets. Overall, however, the relatively small variation among the three estimates of annual clothes washer cycles supported DOE's conclusion that 295 cycles per year was a reasonable value to include in its clothes washer test procedure.

DOE received multiple comments in response to the proposed value of 295 annual cycles. ALS, the Joint Commenters, and Whirlpool support the proposed number of annual cycles. (ALS, No. 10 at p. 2; Joint Commenters, No. 16 at pp. 4–5; Whirlpool, No. 13 at p. 7) BSH also agrees with a value of 295 annual cycles, with the caveat that, if DOE decides to include measurement of self-clean energy and water use in the test procedure, the number of annual cycles will need to be adjusted upwards by the number of self-clean cycles per year suggested by the manufacturer in the product's user manual. (BSH, No. 17 at p. 4) ALS and AHAM questioned the validity of the 2005 RECS data, and requested that DOE work with P&G to secure more recent data. AHAM stated that P&G would be updating the clothes washer use study based on 2010 data. However, AHAM supports the proposed 295 annual cycles because it is likely that the number of cycles has decreased since the P&G data from 2005. (AHAM, No. 14 at pp. 11–12; ALS, No. 10 at pp. 2–3) However, NEEA and the National Institute of Standards and Testing (NIST) noted that the RECS and P&G data both dated from about 2005. (NEEA, Public Meeting Transcript, No. 20 at p. 112; NIST, Public Meeting Transcript, No. 20 at p. 112). Whirlpool stated that 295 cycles per year is consistent with the reduction in average household size. (Whirlpool, No. 13 at p. 7) The Joint Commenters stated that they had conducted their own analysis using the 2005 RECS data, which also resulted in an estimate of 295 annual clothes washer cycles. The Joint Commenters believe that the 2005 RECS data provide a reasonably accurate value in the absence of better data, and that the 2005 RECS data, derived from a national survey, are more representative than the California RASS data that captured usage from one state. (Joint Commenters, No. 16 at pp. 4–5).

NEEA objected to DOE's proposal for 295 annual clothes washer use cycles because NEEA believes that the 2005 RECS survey methods are flawed. According to NEEA, the relatively large bin sizes provided in the survey for the number of laundry loads per week introduces too much uncertainty regarding the average weekly number within each bin. NEEA further stated that it would not automatically discount California RASS data on the basis that the survey represents only one state. NEEA added, however, that it is not familiar enough with the California RASS data, and can not comment on the suitability of using the data to determine average annual use cycles. NEEA commented that it supports using P&G data due to P&G's longtime work in this area and the scope and detail in its survey. NEEA's interpretation of the P&G data results in an estimate of 308 annual clothes washer use cycles, which according to NEEA is similar to the approximately 310 annual cycles derived from recent data collected by the California Public Utilities Commission (CPUC). NEEA noted that while the average household size in the P&G sample is larger than those indicated by the U.S. Census and the American Housing Survey in 2007, it would be logical for households with clothes washers to be larger than average. NEEA also recommended that DOE acquire field data itself to determine annual clothes washer use cycles. (NEEA, No. 12 at pp. 10–11; NEEA, Public Meeting Transcript, No. 20 at pp. 113–114; NEEA, No. 26 at pp. 9–10).

In considering these comments, DOE notes that an independent analysis of the 2005 RECS data by the Joint Commenters resulted in essentially an identical estimate of the number of annual clothes washer cycles as DOE proposed in the September 2010 NOPR. This suggests that DOE's calculation of average annual cycles based on the weekly usage data did not introduce any systematic error in the final value of annual clothes washer cycles. DOE has also reviewed the clothes washer data recently collected in Southern California as part of SDG&E's ''High Efficiency Clothes Washer Voucher Incentive Program'' and PG&E's ''Mass Markets Residential Program.'' [9] Both programs used a combination of telephone surveys and onsite metering to determine the impact of high efficiency clothes washers on energy and water consumption. As part of the telephone surveys, program participants were asked to self-report the number of weekly wash loads. The results for these surveys, from Table 30 in the CPUC report, are shown in Table III.1 below.

TABLE III.1—SELF-REPORTED WASH LOADS FROM 2009 SOUTHERN CALIFORNIA TELEPHONE SURVEYS

Utility	Number of participants	Average number wash loads/week
PG&E	422	5.84
SDG&E	301	5.80
Total ...	723	5.82

Multiplying the average self-reported number of wash loads per week by 52 weeks per year would result in 303 annual clothes washer use cycles. This value can be compared to the results of the onsite metering studies conducted under the PG&E and SDG&E programs during the spring and early summer of 2009. These programs also recorded the actual number of wash loads per week, based on energy and water meter data, at 115 residential sites chosen to include both participants and non-participants in the utility incentive programs. The results from Table 20 in the CPUC report, disaggregated by participant status as well as clothes washer efficiency, are presented in Table III.2.

TABLE III.2—MEASURED WASH LOADS FROM 2009 SOUTHERN CALIFORNIA METERING STUDIES

Category	Efficiency	Number. of sites	Number wash loads/week
Non-Participants	Non-ENERGY STAR	24	4.77
	ENERGY STAR	17	6.23
	Sub-Total	41	5.38
Participants	ENERGY STAR	74	4.80
Weighted Average for all Sites			5.01

On average, subjects in the metering studies performed (5.01 loads per week) × (52 weeks per year) = 261 annual clothes washer loads, which is lower than the self-reported annual use cycles. Although in general, metering data has a higher confidence level than survey results, DOE also notes that the sample size of the onsite study was relatively small, and there was significant variation within that sample. For example, the annual use cycles for non-participants was found to range from 248 for consumers with non-ENERGY STAR clothes washers to 324 for consumers with ENERGY–STAR clothes washers. Further, the data were also collected in a limited geographical region and over only a portion of the year, and may not be fully representative of national clothes washer usage over a complete year.

For these reasons, DOE has determined that the 2005 RECS report is the most representative source of information on annual clothes washer cycles, and is adopting a value of 295 annual cycles in today's final rule.

ASAP questioned whether the proposed value of 295 annual clothes washer cycles corresponds to the number of clothes dryer cycles proposed in the amended DOE clothes dryer test procedure, accounting for the dryer usage factor. (ASAP, Public Meeting Transcript, No. 20 at p. 115) DOE adopted an amended clothes dryer test procedure in a final rule published in the **Federal Register** on January 6, 2011. (76 FR 972) In the amended test procedure, DOE revised the number of clothes dryer annual use cycles from the 416 cycles per year, previously specified by the clothes dryer test procedure, to 283 cycles. (10 CFR 430.23(d)) DOE based this revision on analysis of data from the 2005 RECS for the number of clothes washer cycles and the frequency of clothes dryer use. According to DOE's analysis of 2005 RECS data, for households with both a clothes washer and clothes dryer, the percentage of

[9] The results of these and other 2006–2008 residential energy efficiency programs run by the Investor-Owned Utilities in California are summarized in a report to the CPUC: ''Residential Retrofit High Impact Measure Evaluation Report'', The Cadmus Group, Inc., Itron, Jai J. Mitchell Analytics, KEMA, PA Consulting Group, and Summit Blue Consulting, LLC, February 8, 2010.

clothes washer loads dried in a clothes dryer is 96 percent. Therefore, adopting 295 annual clothes washer use cycles in today's final rule is consistent with the amended clothes dryer test procedure.

DOE also notes that the dryer usage factor in the clothes washer test procedure adopted in today's final rule is 0.91. This value is also based on analysis of 2005 RECS data, but applies to all households with a clothes washer, as explained in more detail in section III.C.3.e of this rule.

Test Load Size Specifications

The current DOE clothes washer test procedure specifies the test load size for the active washing mode energy tests based on the clothes washer's container volume. The table specifying the test load sizes in the test procedure, Table 5.1, currently covers clothes washer container volumes only up to 3.8 ft^3. DOE is aware that multiple clothes washers available on the market have container volumes exceeding 3.8 ft^3.

In the September 2010 NOPR, DOE proposed extending Table 5.1 to accommodate larger clothes washer capacities, up to 6.0 cubic feet. The relationship between test load size and clothes washer volume is linear in Table 5.1 in appendix J1; DOE determined preliminarily that these values were appropriate, and that using a linear extension for larger load sizes would be valid. The proposed amendment extended the linear relationship between test load size and clothes washer container volume currently in the DOE clothes washer test procedure.

In the August 2011 SNOPR, DOE proposed some minor adjustments to the proposed extension of Table 5.1 to correct for inconsistent decimal places in the minimum and maximum load size values, which subsequently affected the calculation of some of the average load sizes. DOE proposed to amend the extension to Table 5.1 by specifying each load size value to the hundredths decimal place.

AHAM, ALS, and Whirlpool support the proposed linear extension of the test load size in Table 5.1. AHAM, ALS, EarthJustice, and NRDC agreed that DOE should extend Table 5.1 to accommodate clothes container volumes up to 6.0 ft^3. Whirlpool stated that test load size has been the subject of several test procedure waivers granted by DOE over the last six years, and that DOE's responses have been consistent with the proposed extension of Table 5.1. According to Whirlpool, the linear relationship remains valid because the majority of clothes washers sold today are adaptive fill machines, which use only the amount of water required by the load size. Furthermore, consumers continue to wash some small loads in the higher-capacity machines. For that reason, Whirlpool suggested, for example, that the 7.8 percent increase in average test load size from a 3.0 ft^3 to 3.3 ft^3 clothes washer is reasonable even though capacity increased by 10 percent. Whirlpool does not believe that the test procedure is biased to favor large-capacity clothes washers. AHAM stated that DOE should ensure that the test procedure does not contain a bias towards large-capacity machines. (AHAM, No. 2 at p. 23) EarthJustice and NRDC support AHAM's statement. (AHAM, No. 2 at p. 23; AHAM, No. 4 at p. 4; AHAM, No. 14 at p. 12; AHAM, Public Meeting Transcript, No. 20 at pp. 122–123; AHAM, No. 24 at p. 3; ALS, No. 10 at p. 3; Whirlpool, No. 13 at p. 7; Whirlpool, No. 27 at p. 4; EarthJustice, No. 3 at p. 1; NRDC, No. 8 at p. 1).

LG stated that it supports DOE's proposal for load sizes, but also stated that the maximum load size in Table 5.1 should be the same for all clothes container volumes, with annual usage cycles decreased for machines with larger volumes to reflect a reduced number of loads per year. (LG, Public Meeting Transcript, No. 20 at pp. 122, 124–126).

NIST recommended collecting additional load size data, because consumers who need to do more laundry may purchase the larger clothes washers. (NIST, Public Meeting Transcript, No. 20 at pp. 128–129).

NEEA does not support the proposed linear extension of Table 5.1 up to clothes container volumes of 6.0 ft^3. NEEA commented that there are no data to suggest that maximum load sizes would extend to 24 pounds, and that there is no demonstrable correlation at this time between clothes container volume and load weight or load volume. NEEA stated that many households do some laundry loads when they run out of clean clothes, or particular clothing items, regardless of the load size or clothes washer capacity. NEEA recommended that DOE prescribe an average test load size that is based on P&G data. (NEEA, No. 12 at p. 11; NEEA, No. 26 at p. 10).

The California Utilities, Energy Solutions (ES), the Joint Commenters, NEEA, and NRDC commented that the test load sizes in Table 5.1 may create an unwarranted bias towards larger-capacity clothes washers. The California Utilities and NRDC objected to the maximum load sizes being a fixed percentage of total capacity, while the average test load size is calculated as the average of a fixed minimum load and the maximum load. The California Utilities, NRDC, and the Joint Commenters provided values for the average test load size as a percentage of capacity, which ranged from 63–68 percent for smaller-capacity clothes washers but 54–57 percent for large-capacity machines. NRDC commented that the relationship of load size to capacity may be linear, but it is not proportionate, suggesting that consumers who purchase larger-capacity clothes washers leave more capacity unused. NRDC further commented that it is not sure that there is data to support this conclusion. The California Utilities commented that the average load size is the primary driver of the energy test load due to the load usage factors, and that average load sizes increases with capacity at a slower rate than the increase in maximum load size because the minimum load size remains constant. The California Utilities stated it was not aware of any recent consumer usage data on test load size. ES also expressed concern about the fixed minimum load size for all capacities. (California Utilities, No. 18 at pp. 3–4; California Utilities, No. 25 at pp. 2–3; ES, Public Meeting Transcript, No. 20 at p. 124; Joint Commenters, No. 16 at p. 5; Joint Commenters, No. 23 at p. 1; NEEA, No. 12 at p. 12; NEEA, No. 26 at pp. 10–11; NRDC, No. 8 at p. 1; NRDC, Public Meeting Transcript, No. 20 at pp. 14, 119–121; 126–127).

The Joint Commenters provided calculations for the allowably energy and water consumed per pound of clothes for clothes washers with capacities ranging from 3.0 to 5.5 ft^3, based on the weighted-average test load size and assuming a fixed MEF of 2.0 and a fixed WF of 6.0. According to the Joint Commenters' calculations, under those conditions a 5.5 ft^3 clothes washer with MEF = 2.0 is allowed 10 percent more energy and water per pound of clothes than a 3.0 ft^3 clothes washer with the same MEF rating. The Joint Commenters stated that this could have implications for the ENERGY STAR ratings, if large-capacity clothes washers can more easily achieve ENERGY STAR certification without ensuring better real-world energy and water use. (Joint Commenters, No. 16 at p. 5).

The California Utilities and the Joint Commenters suggested approaches for DOE to revise Table 5.1 to eliminate a possible bias towards larger-capacity clothes washers. The California Utilities recommended that DOE base average test load size on a fixed percentage of clothes container volume, and suggested a value of approximately 65 percent of capacity. The California Utilities further recommended that DOE develop a new

metric based on energy use per pound of clothing washed, rather than energy use as a function of capacity. The California Utilities acknowledged the substantial input required from interested parties and the attendant significant negative impact on the clothes washer test procedure rulemaking schedule, and therefore recommended that DOE consider this approach for a future test procedure rulemaking. (California Utilities, No. 18 at p. 4).

The Joint Commenters suggested three possible alternatives for revising the test load sizes in Table 5.1:

1. Base the average test load size for all washers in a particular product class on the percentage of capacity used by the average test load of the average-sized clothes washer in that product class. The Joint Commenters noted that, according to AHAM, the average shipment-weighted capacity in 2009 was 4.03 ft^3 for front-loaders and 3.66 ft^3 for top-loaders, yielding a capacity utilization (*i.e.,* ratio of average test load weight to maximum test load weight) for the average test load of 59 percent for front-loaders and 60 percent for top-loaders. Maximum test load weights for other clothes washer capacities would be derived using the scaling factor currently used in Table 5.1, approximately 4 pounds per cubic foot of capacity.[10]

2. Base the average test load size for all clothes washers on the average test load size assumed in the RMC calculation in the test procedure (*i.e.,* the average test load size would be 52 percent of the maximum load size).

3. Use the test load sizes in the current Table 5.1, but calculate the average test load size for clothes washers with capacities between 3.8 ft^3 and 6.0 ft^3 using the capacity utilization of the largest machine in the current table (*i.e.,* the average test load size would be fixed at 59.7 percent of the maximum test load size for clothes washers in this capacity range.)

The Joint Commenters requested that DOE test a sample of front-loading and top-loading clothes washers of various capacities using the above-suggested alternatives to compare the resulting energy and water factors with the test results obtained using the proposed test procedure, and if there are substantial differences, DOE should consider revisions to Table 5.1 to reduce the potential for unwarranted bias toward large capacity clothes washers. (Joint Commenters, No. 16 at pp. 6–7).

In the September 2010 NOPR, DOE requested additional consumer data regarding current test load sizes, but it did not receive any such data from interested parties. DOE carefully considered the existing data sources for evaluating minimum, maximum, and average test loads. As noted above, P&G provided data indicating that, in 2003, average consumer load sizes were 7.2 lb for all top-loading clothes washers and 8.4 lb for all front-loading clothes washers. However, the P&G data does not identify average load size as a function of machine capacity, and therefore DOE cannot infer that these values are representative of average consumer load sizes for clothes washers of all capacities available on the market today.

Under the current formulation of the test load sizes, the average load size represents a decreasing percentage of maximum load size as the capacity of the clothes washer increases. Larger-capacity machines can therefore achieve a given MEF/WF rating using larger amounts of water and energy per pound of clothing than smaller-capacity machines with the same MEF/WF rating. Information to suggest that this scenario does not reflect true consumer usage was not available for this rulemaking. Information that would indicate that average consumer clothing load sizes are a fixed percentage of clothes container capacity (and, thus, maximum clothes load size) was also not available. Updated consumer usage data will be necessary to determine whether the numerical advantage for large-capacity clothes washers is justified by real-world use. DOE is aware of ongoing and future planned field studies that are expected to provide updated data regarding the relationship between clothes washer capacity and clothing load size. DOE will consider using data from these field studies in future clothes washer test procedure rulemakings.

Based on available data, DOE determined that a fixed minimum load size is appropriate, given that consumers may desire to wash only a few articles of clothing regardless of the size of their clothes washer. In considering maximum test load sizes, DOE reviewed user manuals for clothes washer models from multiple manufacturers, and noted that the instructions generally included a notation that the clothes container could, and for some cycles, should, be loaded to the point that the clothes container is loosely filled. DOE infers that some consumers will follow these instructions, which will result in a maximum test load size that is proportional to the volume of the clothes container.

For these reasons, DOE has determined that the linear extension of Table 5.1, including the proportional relationship of maximum test load size to clothes washer capacity, a fixed minimum test load size, and calculation of average test load size, currently represents the best possible approach for determining these load sizes. Therefore, today's final rule extends Table 5.1 as proposed in the August 2011 SNOPR in appendix J1 and the new appendix J2. If DOE receives new data that would lead to a different conclusion for the test load sizes specified in Table 5.1, DOE will consider updating the test procedure at that time. The extension of Table 5.1 will also address the waivers and interim waivers currently granted to several manufacturers for testing clothes washers with capacities greater than 3.8 cubic feet.

Load Usage Factors

The load usage factors in the DOE test procedure represent the fraction of all wash cycles a typical consumer runs for the minimum, average, and maximum load sizes. At the time of publication of the September 2010 NOPR, DOE was not aware of any recent data characterizing such usage patterns. Therefore, DOE did not propose any changes to the load usage factors.

NEEA stated that, in the absence of updated data, the existing load usage factors are acceptable, but that DOE should acquire contemporory data to support a validation of the current numbers. (NEEA, No. 12 at p. 10, 12; NEEA, No. 26 at p. 11) AHAM commented that it is not aware of recent data characterizing load size usage patterns, and thus it supports DOE's proposal not to change the load usage factors. (AHAM, No. 14 at p. 12).

For the reasons stated in the September 2010 NOPR, DOE has determined that the load usage factors are the best estimate of usage patterns available at this time. Therefore, DOE is not revising the load usage factors in today's final rule.

Temperature Use Factors

DOE proposed in the September 2010 NOPR to amend the TUFs in the clothes washer test procedure to account for

[10] The comment states that the *average* test load weight should be scaled, but this may be an editing error: In Table 5.1 the scaling factor for average test load weight ranges from 3.5 lb/ft^3 for small capacity to 2.3 lb/ft^3 for large capacity, whereas the scaling factor for maximum test load weight is a constant 4.10 ± 0.03 lb/ft^3.

steam wash cycles, and to revise the warm rinse TUF. Table III.3 shows the TUFs proposed in the September 2010 NOPR.

TABLE III.3—TEMPERATURE USE FACTORS PROPOSED IN THE SEPTEMBER 2010 NOPR

Max wash temp available	≤135 °F (57.2 °C)			>135 °F (57.2 °C)		Steam	
No. wash temp selections	Single	2 Temps	>2 Temps	3 Temps	>3 Temps	3 Temps	>3 Temps
TUF_s (steam)						0.02	0.02
TUF_m (extra hot)				0.14	0.05	0.12	0.03
TUF_h (hot)		0.63	0.14		0.09		0.09
TUF_{ww} (warm/warm)			*0.27	*0.27	*0.27	*0.27	*0.27
TUF_w (warm)			0.22	0.22	0.22	0.22	0.22
TUF_c (cold)	1.00	0.37	0.37	0.37	0.37	0.37	0.37

* Only applicable to machines offering a warm/warm cycle. For machines with no warm/warm cycle, this value should be zero and the warm TUF (TUF_w) should be increased by 0.27.

DOE assumed that the steam wash cycle TUF would affect only the extra-hot TUF, leaving the other TUFs unchanged. DOE discussed its analysis of the data on consumer wash and rinse temperature selections from the 2005 RECS and the 2004 California RASS, both of which provide information on temperature selections. Because the temperature use factors from each source demonstrated general agreement, DOE determined that the current TUFs in its test procedure are a reasonable estimate of current consumer use. DOE therefore proposed to keep the TUFs for cold wash, warm wash, and hot wash unchanged. DOE incorporated the steam cycle TUF by decreasing the value of the extra-hot TUF.

In the September 2010 NOPR, DOE also proposed to revise the methods for measuring warm rinse and to incorporate the revised measurement into the test procedure's calculations. DOE observed that most clothes washers available on the market allow users to select a warm rinse only when it is coupled with a warm wash cycle. DOE, therefore, proposed to establish a TUF for a full warm wash/warm rinse cycle. DOE also proposed to eliminate the incremental use factor attributed to warm rinse, requiring instead the measurement of energy and water consumption over an entire wash/rinse cycle that utilizes warm rinse. DOE proposed using the same warm rinse TUF of 0.27 for the complete warm wash/warm rinse cycle. For those clothes washers with such an option, DOE also proposed to reduce the warm wash/cold rinse TUF by a corresponding amount, lowering it from 0.49 to 0.22. DOE further proposed that the warm wash/warm rinse TUF would not be applicable for clothes washers with one or two wash temperature settings, because those washers would not provide a warm wash/warm rinse cycle. DOE did not propose to amend the TUFs for wash temperature selections other than the warm wash, except for units offering a steam wash cycle as previously described. Additionally, the proposed TUFs for warm/cold and warm/warm would sum to the existing warm wash TUF; overall, the warm wash temperature selection would receive the same weight in the energy and water consumption calculations.

DOE received multiple comments from interested parties in response to the proposed temperature use factors. NEEA expressed concern over the lack of recent consumer usage pattern data, but stated that the existing data do not support changing the TUFs currently provided in the test procedure. NEEA commented that the most important reason to acquire more recent data is that ''hot'', ''warm'', and ''cold'' designations for the energy test cycle do not reflect the current range of options for wash and rinse temperatures. NEEA also expressed concern that the California RASS data may be outdated and the fact that it is based on survey data rather than field data. However, NEEA stated that the most recent California usage data would likely support the current TUFs. (NEEA, No. 12 at p. 12; NEEA, Public Meeting Transcript, No. 20 at p. 131).

NEEA also supports the proposed methodology for measuring water and energy consumption for warm rinse over a complete cycle, with one exception. NEEA does not agree that most clothes washers currently available allow users to select a warm rinse only with a warm wash cycle. NEEA stated it may be appropriate to specify that a separate TUF be established for a hot wash/warm rinse cycle, a hot wash/warm rinse/steam cycle, or a warm wash/warm rinse/steam cycle. (NEEA, No. 12 at p. 12).

BSH commented that consumer use is well-represented by measuring cold, warm, and possibly hot wash cycles specified for cotton or ''normal'' fabrics, for the following reasons:

1. Many customers run one low-energy cycle, such as a ''delicates'' or ''hand-wash'' program, per week.

2. Many customers also run one or more ''permanent press'' or similar program per week, which is typically equal to or lower in energy than the cotton program.

3. Other special programs that use more or less energy or water than the cotton program are run very infrequently.

4. Basing MEF on only the cotton or normal programs is already over-reporting energy use versus actual consumer behavior.

(BSH, No. 17 at p. 5).

Whirlpool commented that DOE must use data that are representative of currently manufactured clothes washers rather than data that are 15 or more years old. Whirlpool stated that it had provided data to DOE that suggested a TUF of 0.016 (1.6 percent) for warm rinse, and that this percentage is representative of its clothes washers. Whirlpool also noted that it is the largest manufacturer of clothes washers in the United States, with a 64 percent market share, and it only offers a warm rinse option on approximately 9 percent of its clothes washers. According to Whirlpool, for the 27 percent TUF for warm rinse to be valid, its competitors would have to offer warm rinse on over 60 percent of their machines and all consumers would have to select warm rinse if it were offered. (Whirlpool, No. 13 at pp. 8–11).

AHAM, ALS, and Whirlpool stated that the proposed warm wash/warm rinse TUF of 0.27 is too high, and that a warm rinse option has become increasingly rare in clothes washers currently available on the market. ALS, AHAM, and Whirlpool further commented that data from Natural

Resources Canada (NRCan) show that both wash and rinse temperatures are decreasing over time. According to AHAM and Whirlpool, for all clothes washers in 2007, the NRCan data shows warm rinse to be the most frequent selection only 16 percent of the time, which is a decrease from 23 percent in 1993. AHAM, ALS, and Whirlpool commented that NRCan data is relevant to U.S. consumer usage patterns because Canadian clothes washer designs are the same as those in the United States and consumer practices are similar. (AHAM, No. 14 at pp. 12–13; ALS, No. 10 at p. 4; Whirlpool, No. 13 at pp. 8–11; Whirlpool, Public Meeting Transcript, No. 20 at pp. 133–134).

BSH commented that it supports the use of the NRCan data for determining the TUFs, and that the conclusions AHAM has drawn from the data agree well with BSH's customer feedback. (BSH, No. 17 at p. 4) LG stated that DOE could infer warm rinse usage from the percentage of detergent purchases that are cold water formulations. According to LG, if, for example, 85 percent of the detergent purchased in the United States were cold-water detergent, DOE could assume that the warm rinse TUF is very low. (LG, Public Meeting Transcript, No. 20 at p. 133) China requested that DOE clarify the TUF for steam, extra-hot, hot, warm, and cold wash cycles as well as warm wash/warm rinse and other wash modes. (China, No. 19 at p. 4).

DOE re-examined the 2005 RECS data to determine whether the usage patterns show a reduction in warm rinse usage for newer machines, of which, according to Whirlpool, a smaller percentage are including a warm rinse option. As shown in Table III.4, there is no correlation in the 2005 RECS data between the age of the clothes washer and the percentage of users reporting that they usually select warm rinse. The percentage of users reporting that they usually select warm rinse ranged from 19.1 to 21.5 percent. These data suggest that the introduction of newer models to the installed base did not affect consumer usage of warm rinse, at least during the time frame covered by the survey (*i.e.,* until 2005).

TABLE III.4—2005 RECS DATA ON THE USE OF WARM RINSE BY AGE OF THE CLOTHES WASHER

Age of clothes washer	Percentage of users that usually use warm rinse
Less than 2 years old	21.5
2 to 4 years old	19.1
5 to 9 years old	19.2
10 to 19 years old	19.9
20 years or older	21.4

DOE further notes that the TUF for warm rinse is applicable only to those clothes washers that provide a warm rinse option (i.e., the warm rinse TUF represents the percentage of laundry loads for which a consumer selects the warm wash/warm rinse temperature combination on machines that offer a warm rinse option). Therefore, DOE disagrees with Whirlpool's statement that for the 27-percent TUF for warm rinse to be valid, its competitors would have to offer warm rinse on over 60 percent of their machines and all consumers would have to select warm rinse if it were offered. The intention of the TUFs is to represent typical consumer usage patterns of individual clothes washer models with a specific set of temperature options, not the average consumer usage patterns across all types of clothes washer models.

DOE also reiterates that the survey data indicating warm rinse usage of 1.6 percent are based on a single clothes washer model from a single manufacturer, and that this clothes washer model does not offer the warm rinse option on the cycle recommended for cotton or linen clothes. Commenters provided no additional data to demonstrate that this conclusion would be valid for all clothes washer models offering a warm rinse, including clothes washers that offer a warm rinse option on the cycle recommended for cotton or linen clothes.

DOE does not have any information to determine what percentage of respondents in either the NRCan or 2005 RECS surveys who stated that they usually used cold rinse cycles were using machines equipped with a warm rinse option. DOE believes it is reasonable to assume that at least some consumers with cold rinse-only clothes washers were included in the survey samples, and thus, if those respondents were discounted, the percentage of users selecting warm rinse would be even higher than the estimates shown above. Given the disparity between the results for warm rinse usage from the NRCan and 2005 RECS surveys and the data submitted by Whirlpool, DOE concludes that there is a lack of evidence on which to base a decrease in the existing TUF value, as suggested by Whirlpool.

As discussed in section III.C.2.a, DOE is not amending the test procedure to measure energy and water use in steam wash cycles. Thus, in the absence of sufficient data on recent consumer usage patterns to warrant changing the TUFs, and because DOE is not adopting provisions to measure steam wash cycles, DOE is retaining the TUFs that are provided in the existing test procedure at appendix J1, with the modification that the warm/warm TUF will be treated as a complete wash/rinse cycle, and the warm/cold TUF adjusted accordingly when a warm/warm cycle is available on the clothes washer.

DOE considered the possibility of requiring measurement of a hot wash/warm rinse cycle as part of the energy test cycle, and assigning a TUF accordingly. DOE's analysis of 2005 RECS data indicates that the percentage of all respondents who usually select a hot wash/warm rinse cycle is 1.8 percent. DOE does not believe that this small percentage would warrant the additional test burden associated with measuring a hot wash/warm rinse cycle and including such energy and water consumption in the test procedure calculations. Accordingly, DOE is not adopting a TUF for hot wash/warm rinse in today's final rule.

Dryer Usage Factor

DOE proposed in the September 2010 NOPR to amend its clothes washer test procedure to include a dryer usage factor (DUF) of 0.91, based on the 2005 RECS. DOE proposed to use the value derived from the 2005 RECS, rather than the 2004 California RASS, because the 2004 California RASS is inconsistent with the proposed number of wash cycles per year and because the 2005 RECS data represent the entire country rather than one state.

NEEA agreed with DOE's methodology for deriving the proposed DUF. (NEEA, No. 12 at p. 12) AHAM stated that it does not oppose the proposed DUF, but commented that DOE should be relying on more representative data than that in the 2005 RECS. (AHAM, No. 14 at p. 13) ALS opposed the proposed DUF, questioning the validity of the 2005 RECS data. ALS supports retaining the existing value of 0.84, in the absence of other data. (ALS, No. 10 at p. 4) ALS did not provide any further information on why it believes the 2005 RECS data may be invalid. DOE has determined that 2005 RECS data is the best available data that reasonably captures the dryer usage practices of consumers using residential

clothes dryers, and is thus adopting a revised DUF of 0.91 in the amended test procedure in this final rule.

Load Adjustment Factor

The load adjustment factor (LAF) represents the ratio of maximum load size to average load size. This ratio is used in the calculation of the energy required to remove moisture from the test load. The RMC value used in this calculation is based only on tests using the maximum test load, and the LAF is used to scale this value down to represent the average load size. In the September 2010 NOPR, DOE noted that it lacked information warranting adjustment of this value or a change from a fixed value to one that varies as a function of average load size, and therefore did not propose to amend the LAF in the test procedure.

In response to the September 2010 NOPR, DOE received numerous comments regarding the LAF, which were summarized in the August 2011 SNOPR. Upon consideration of these comments, DOE determined that the LAF is duplicative of, yet inconsistent with, the load usage factors. Therefore, for consistency with other relevant provisions of the test procedure, DOE proposed in the August 2011 SNOPR that the representative load size calculation in the equation for drying energy incorporate the load usage factors rather than a separate LAF. DOE proposed that the current representative load size calculation be replaced by the weighted-average load size calculated by multiplying the minimum, average, and maximum load usage factors by the minimum, average, and maximum load sizes, respectively, and summing the products.

DOE received the following comments in response to the proposed elimination of the LAF in the August 2011 SNOPR:

AHAM and ALS support the approach of using a weighted-average load size in the calculation of dryer energy use, but note that the new approach will increase the measured energy. AHAM and ALS added that DOE must revise the relevant energy conservation standard to reflect the new test procedure, ensuring that there is no change in the stringency of the standards based on average energy consumption calculations before and after the changes to the test procedure. ALS suggested revising only appendix J2 with this change, noting that there is still time to consider this impact in the updated minimum efficiency standards. (AHAM, No. 24 at p. 4; ALS, No. 22 at pp. 2–3).

Whirlpool stated that it would oppose the proposal to use a weighted-average load size for the purposes of calculating drying energy if it would require testing for RMC on the average and minimum load sizes in addition to the maximum load size. Whirlpool stated that such a requirement, if adopted, would triple the RMC testing required, adding at least one full day to the test time for each base model. Whirlpool added that DOE's proposal would not increase the test burden if it requires only testing RMC at the maximum load size. Whirlpool also recommended that this amendment be made only to appendix J2. (Whirlpool, No. 27 at p. 3).

The Joint Commenters, California Utilities, and NEEA support DOE's proposal to replace the representative load size based on the load adjustment factor with a weighted-average load size to calculate dryer energy use. The Joint Commenters and the California Utilities noted, however, that this proposed change would result in a greater increase in the representative load size used to calculate dryer energy consumption for small capacity washers than for large-capacity washers, which would therefore make any potential bias towards large-capacity washers more significant. The Joint Commenters added that they are not aware of any data indicating that consumers utilize a smaller percentage of the washer capacity when using large-capacity machines compared to smaller machines, nor of any data indicating it is more difficult for larger-capacity machines to achieve high efficiency ratings. In the absence of such data, the Joint Commenters recommended that the weighted-average load size as a percentage of total capacity be kept constant across all washer capacities. (Joint Commenters, No. 23 at p. 4; California Utilities, No. 25 at p. 3; NEEA, No. 26 at p. 5).

For the reasons stated in the August 2011 SNOPR, DOE replaces the representative load size calculation with the weighted average load size calculated using the load usage factors. This change applies only to the newly created appendix J2. This approach will not require measuring the RMC for any additional load sizes, and therefore will not increase manufacturer test burden.

4. Energy Test Cycle Definition

The ''energy test cycle'' consists of the wash cycles currently used in determining the modified energy factor (MEF) and water factor (WF) for a clothes washer, and proposed to be used for determining integrated modified energy factor (IMEF) and integrated water consumption factor (IWF). The energy test cycle is defined in section 1.7 of the current clothes washer test procedure as follows:

''1.7 *Energy test cycle* for a basic model means (A) the cycle recommended by the manufacturer for washing cotton or linen clothes, and includes all wash/rinse temperature selections and water levels offered in that cycle, and (B) for each other wash/rinse temperature selection or water level available on that basic model, the portion(s) of other cycle(s) with that temperature selection or water level that, when tested pursuant to these test procedures, will contribute to an accurate representation of the energy consumption of the basic model as used by consumers. Any cycle under (A) or (B) shall include the agitation/tumble operation, spin speed(s), wash times, and rinse times applicable to that cycle, including water heating time for water heating clothes washers.''

In the September 2010 NOPR, DOE proposed to amend Part (B) of the energy test cycle definition to clarify the wash parameters that should be considered to determine which cycle settings should be included under Part (B) of the definition.

In additional testing after the publication of the September 2010 NOPR, DOE observed that some clothes washers retain in memory the most recent options selected for a cycle setting the next time that cycle is run. To ensure repeatability of test results, particularly for cycles under Part (B) of the energy test cycle definition, DOE proposed in the August 2011 SNOPR to provide further clarification that the manufacturer default conditions for each cycle setting shall be used, except for the temperature selection, if necessary.

DOE received multiple comments from interested parties regarding its proposed changes to the energy test cycle definition. The comments generally indicated that the proposed revisions to the definition still lacked clarity. In response to the August 2011 SNOPR, Whirlpool, GE, and ALS jointly proposed a modified definition of the energy test cycle which eliminated what these commenters perceived as a primary source of ambiguity in DOE's previously proposed definition. (GE, Whirlpool, & ALS, No. 28 at pp. 1–2) Because of the scope of the manufacturers' proposed changes, and because the energy test cycle definition is a critical component of the test procedure, DOE incorporated the manufacturers' suggestions into a new definition, proposed in the November 2011 SNOPR. The most notable proposed change involved Part (B) of the energy test cycle definition, which DOE proposed as follows:

''(B) If the cycle setting described in (A) does not include all wash/rinse temperature

combinations available on the clothes washer, the energy test cycle shall also include the alternate cycle setting(s) offering these wash/rinse temperature combination(s), tested at the wash/rinse temperature combinations not available on the cycle setting described in (A).

Where multiple alternate cycle settings offer a wash/rinse temperature combination that is not available on the cycle setting recommended by the manufacturer for washing cotton or linen clothes, the cycle setting certified by the manufacturer to have the highest energy consumption, as measured according to section 2.13, shall be included in the energy test cycle.''

DOE stated that this proposed new definition would provide further clarity and produce more accurate, repeatable, and reproducible results within and among all test laboratories.

DOE also proposed a new section 2.13, which would provide instructions for determining the cycle setting with the highest energy consumption in the case where multiple alternate cycle settings offer a wash/rinse temperature combination not available on the cycle setting recommended by the manufacturer for washing cotton or linen clothes.

In the November 2011 SNOPR, DOE responded to prior comments received in response to the September 2010 NOPR and August 2011 SNOPR. DOE received the following comments in response to the November 2011 SNOPR:

NEEA commented that it supports DOE's decision to keep Part (B) of the energy test cycle definition, and stated that all cycle selections for which a TUF has been developed should be included in the energy test cycle. NEEA recommended that DOE ensure that manufacturer default settings are chosen for selections other than water temperature, particularly for parameters that would affect RMC, since a large fraction of total energy use is derived from RMC. NEEA believes this is especially important since DOE proposed to use only machine and hot water energy use as the criteria for determining which of the alternate cycle settings has the highest energy use. NEEA added that it believes DOE adequately evaluated the potential test burden impact on manufacturers, and it does not believe that the proposed test procedure modifications will create additional test burden on any manufacturers. (NEEA, No. 31 at p. 2).

AHAM commented that the newly proposed energy test cycle definition would not provide any further clarity to manufacturers. AHAM and GE suggested that further clarification of the language in several areas would be necessary to ensure the test procedure is repeatable and representative of consumer behavior. In particular, AHAM suggested that the definition should explicitly state that all temperature selections corresponding to the TUFs, which are available on a product, be tested only once, and that they should be tested only during the ''Normal'' cycle if possible. (AHAM, No. 34 at p. 2; GE, No. 35 at p. 1).

Whirlpool reiterated its comment from the August 2011 SNOPR that the language of Part (A) of the current energy test cycle definition in appendix J1 is adequate and that Part (B) does not add value. Whirlpool also stated, however, that it agrees with DOE that the language in Part (B) of the current energy test cycle definition in appendix J1 is unclear and subject to varying interpretations. Whirlpool commented that as written, DOE's proposal would not reflect real-world consumer use and would increase manufacturer test burden by 3–4 times. Whirlpool stated that it believes DOE did not intend in its proposed language to require testing the maximum energy-consuming cycles for all possible temperature combinations on a product; rather, the scope for inclusion of test cycles beyond the ''Normal'' cycle should logically be limited to temperature selections for which a TUF has been developed. Whirlpool added that limiting cycle selection to already-existing TUFs would eliminate the need for exhaustive testing, which would reduce test burden and be more representative of consumer usage. (Whirlpool, No. 33 at pp. 1–2).

After reviewing comments from interested parties, DOE notes that it intended its proposed definition to require the testing of all temperature selections available on a product for which a TUF has been developed. *See* 76 FR 69870, 69875. DOE also agrees with commenters who suggested that each TUF should be tested only once and that each TUF should be tested using the ''Normal'' cycle if possible. DOE did not intend for the revised definition to require the testing of all temperature combinations within all the cycle selections available on a machine. DOE concurs that this would have resulted in a significant increase in test burden.

DOE has amended the language of the energy test cycle in today's final rule accordingly. These amendments are largely consistent with the suggested amendments from manufacturers, as described in more detail in the following sections.

Regarding the use of manufacturer default settings, DOE concurs with NEEA that the manufacturer default settings for selections other than water temperature should be used, including during testing under the new section 2.13 to determine which of the alternate cycle settings has the highest energy use. Today's final rule specifies in both the energy test cycle definition and in section 2.13 that the manufacturer default settings should be used for all wash parameters other than temperature selection.

The following sections describe comments received in regard to each of the individual parts of DOE's proposed definition of the energy test cycle, as well as comments regarding the new section 2.13 and the proposed revision to manufacturer reporting requirements. DOE's responses to comments are provided in each section.

Part (A) of the Proposed Definition

AHAM proposed modifying Part (A) to clarify that it applies only to temperature selections for which TUFs have been developed, as follows:

''(A) The cycle setting recommended by the manufacturer for washing cotton or linen clothes, including all wash/rinse temperature selections for each of the temperature use factors (TUFs) offered in that cycle setting, and''

(AHAM, No. 34 at p. 6)

DOE believes that AHAM's proposed modification would add clarity to the energy test cycle definition while maintaining consistency with the intent of DOE's proposed definition. The proposed modification would also maintain consistency with the original intent of Part (A) as defined in the current test procedure at appendix J1. Therefore, this final rule adopts AHAM's proposed clarification for Part (A) of the energy test cycle definition in appendix J2.

Part (B) of the Proposed Definition

AHAM and GE requested clarification of the term ''temperature combination'' in the second paragraph of Part (B) in relation to the term ''temperature selection'' in Part (A). AHAM proposed maintaining consistency in the language in order to avoid ambiguity from using two words with the same meaning. AHAM requested that the term ''temperature selection'' be used instead, believing that it is clearer and more representative. (AHAM, No. 34 at p. 2; GE, No. 35 at p. 2).

AHAM, ALS, and GE requested clarification of the phrase ''shall also include'' in Part (B) of the energy test cycle definition. ALS commented that it is unclear as to whether the phrase ''shall be included'' means to directly add the energy of Part (B) to Part (A), or to average the energy from Parts (A) & (B), or to apply an unknown usage factor to Part (B). (AHAM, No. 34 at p. 2; ALS,

No. 32 at p. 1; GE, No. 35 at p. 2) Whirlpool commented that averaging all cycles used by consumers would be unduly burdensome and would not provide any appreciable difference in results than would be derived from Part (A) of the current energy test cycle definition in appendix J1. (Whirlpool, No. 33 at p. 1).

AHAM proposed modifying Part (B) by specifying that Part (B) applies only to temperature selections for which TUFs have been developed, and that each TUF available on the product should be tested only once. GE commented that it agrees with AHAM's proposed modifications. Whirlpool also suggested specifying that Part (B) applies only to temperature selections for which TUFs have been developed. (AHAM, No. 34 at p. 6; GE, No. 35 at p. 2; Whirlpool, No. 33 at p. 2).

AHAM proposed the following language for Part (B), which also incorporates the suggested edits of Whirlpool:

''(B) If the cycle setting described in Part (A) does not include all wash/rinse temperature selections for each of the TUFs available on the clothes washer, the energy test cycle shall also include the alternate cycle setting(s) offering these remaining wash/rinse temperature selection(s), tested at the wash/rinse temperature selections for each TUF or TUFs not available on the cycle setting described in Part (A).

Where multiple alternate cycle settings offer a wash/rinse temperature selection for which a TUF has been developed and that is not available on the cycle setting recommended by the manufacturer for washing cotton or linen clothes described in Part (A), the alternate cycle setting certified by the manufacturer to have the highest energy consumption for that TUF, as measured according to section 2.13, shall be included in the energy test cycle so that each TUF that is available on the product has been tested once.''

(AHAM, No. 34 at p. 6)

DOE notes that Part (B) of its proposed definition uses the term ''temperature combination'' instead of the term ''temperature selection,'' which is used in Part (A). In addition, the term ''temperature selection'' implies a setting on the machine that a user would select, whereas ''temperature combination'' could be interpreted to mean the actual temperature experienced inside the wash drum for a given temperature selection. This could create confusion if a temperature selection on the machine provides different actual temperatures depending on which cycle selection is chosen. For example, a hot/cold temperature selection could provide a wash temperature of 120 °F on the Cottons setting with a 60 °F rinse temperature, yet provide a higher wash temperature of 135 °F on the Heavy Duty setting with a 60 °F rinse temperature. In this case, ''temperate selection'' would refer to the single labeled hot/cold selection on the machine, whereas ''temperature combination'' could be interpreted to mean both the 120/60 °F wash/rinse temperature combination and the 135/60 °F temperature combination. The intent of DOE's proposed definition of the energy test cycle is to require the testing of each wash/rinse temperature selection as labeled on the machine's control panel, rather than requiring the testing of every single temperature combination that occurs among all the different cycle selections on the machine. Therefore, today's final rule uses the term ''temperature selection'' consistently throughout the energy test cycle definition.

Similarly, DOE is concerned that the term ''cycle setting'' could also introduce ambiguity into the definition. DOE had proposed to use the term ''cycle setting'' rather than the term ''cycle,'' which is used in the current appendix J1 definition, to differentiate between the labeled cycles on a machine (*i.e.,* Normal, Whites, Colors, Heavy Duty, etc.) and a single active mode laundry cycle, which is commonly referred to as a ''cycle.'' DOE has observed that user manuals from manufacturers representing a significant portion of the market refer to the labeled cycles as ''cycles'' (*i.e.,* the ''Normal cycle'', ''Whites cycle'', ''Colors cycle,'' etc.). Because of this, a ''cycle setting'' could be interpreted to mean a specific temperature, soil level, spin speed, or other setting within the labeled cycle. Therefore, to prevent this possible ambiguity, today's final rule instead uses the term ''cycle selection'' to mean the labeled cycle on the machine.

As discussed previously, DOE intended its proposed definition to require the testing of all temperature selections available on a product for which a TUF has been developed. DOE also agrees with commenters that each TUF should be tested only once and that each TUF should be tested using the ''Normal'' cycle if available. Therefore, DOE supports AHAM and the manufacturers' suggested modifications to Part (B), which specify that Part (B) applies only to temperature selections for which TUFs have been developed, and that each TUF available on the product should be tested only once. Therefore, today's final rule adopts AHAM's proposed clarifications for Part (B) of the energy test cycle definition in appendix J2.

Based on comments from AHAM and manufacturers regarding confusion about how the energy results from Part (B) are to be included in the energy test cycle, today's final rule replaces the phrase ''shall also include * * *'' with the phrase ''shall include, in addition to Part (A) * * *.'' DOE believes that this change, coupled with the clarification that Part (B) applies only to the TUFs not available in the cycle selection used for Part (A), will remove ambiguity about how to include the test results for Part (B). Consistent with the current appendix J1 test procedure, the energy and water consumption measured under Part (B) of the energy test cycle should be weighted by the appropriate TUF and added to the weighted energy and water consumption measured under Part (A).

Part (C) of the Proposed Definition

DOE did not receive any comments from interested parties regarding Part (C) of the proposed definition of the energy test cycle. Today's final rule modifies DOE's proposed language for Part (C) by revising the reference to ''Part (A) and Part (B)'' so that Part (C) reads as follows:

''All cycle selections included under Part (A) and all cycle selections included under Part (B) shall be tested using each appropriate load size as defined in section 2.8 and Table 5.1 of this appendix.''

Because Part (A) refers to the specific cycle selection recommended by the manufacturer for washing cotton or linen clothes, and Part (B) refers to other alternate cycle selection(s), none of the cycle selections included in the energy test cycle would be tested under both Part (A) and Part (B). The revised Part (C) is applicable to the cycle selected under Part (A) and all cycles included separately under Part (B).

Part (D) and Part (E) of the Proposed Definition

Whirlpool agrees with DOE's proposal to specify that each cycle included as part of the energy test cycle comprises the entire active washing mode, and excludes any delay start or cycle finished modes. (Whirlpool, No. 33 at p. 2)

NEEA disagrees with DOE's proposal to exclude delay start and cycle finished modes as part of the active mode in the energy test cycle definition. NEEA believes that these modes should be tested and assigned appropriate usage factors. NEEA stated that certain clothes washers offer delayed start and cycle finished mode options not available in the normal cycle. NEEA acknowledged, however, the lack of available data on delayed start and cycle finished mode, and stated its intention to gather data on these modes for inclusion in the energy test cycle definition during the next

opportunity to improve the test procedure. (NEEA, No. 31 at p. 2).

For the reasons described previously in sections III.B.2.b and III.B.2.c, today's final rule does not require testing of delayed start or cycle finished modes. Therefore, today's final rule is consistent with DOE's proposal to specify that each wash cycle included as part of the energy test cycle comprises the entire active washing mode, and excludes any delay start or cycle finished modes. In today's final rule, this clarification is provided in a new Part (E) of the energy test cycle definition.

In addition, as described previously in section III.B.2.d, today's final rule also does not require the testing of self-clean mode. Therefore, today's final clarifies that the energy test cycle shall not include any cycle, if available, that is dedicated for cleaning, deodorizing, or sanitizing the clothes washer, and is separate from clothes washing cycles. This should prevent confusion as to whether the self-clean cycle should be considered eligible for testing under Part (B) if, for example, the self-clean cycle used one of the temperature selections not available in the cycle tested in Part (A) (*e.g.* extra-hot). In today's final rule, this clarification is provided in a new Part (F) of the energy test cycle definition.

New Section 2.13

AHAM proposed modifying the language in the newly proposed section 2.13 by: (1) Using the term ''temperature selection'' instead of ''temperature combination''; (2) specifying that testing under section 2.13 applies only to temperature selections for which TUFs have been developed and TUFs not represented in the cycle setting represented in Part (A) of the energy test cycle definition; and (3) specifying that each TUF available on the product should be tested only once. Whirlpool also suggested clarifying that section 2.13 applies only to temperature selections for which TUFs have been developed. GE commented that it agrees with AHAM's proposed modifications for section 2.13. (AHAM, No. 34 at pp. 6–7; Whirlpool, No. 33 at p. 2; GE, No. 35 at p. 2)

For the reasons described in the previous sections regarding the energy test cycle definition, DOE concurs with AHAM and manufacturers' suggestions regarding the term ''temperature selection'' and the need to specify that testing under section 2.13 applies only to temperature selections for which TUFs have been developed and which are not represented in the cycle tested under Part (A).

DOE has determined that it is unnecessary and potentially confusing to modify the language in section 2.13 to specify that each TUF available on the product should be tested only once. The provisions set forth in Part (B) of the revised definition of energy cycle clarify that each TUF shall be tested once. DOE notes, however, that each TUF being considered under the exploratory testing provisions of section 2.13 might need to be tested on different cycle selections to determine which cycle selection uses the most energy. For these reasons, DOE does not adopt the proposed clarification in section 2.13 that each TUF available on the product should be tested only once.

Today's final rule also modifies the structure of section 2.13 by separating the individual provisions into subsections 2.13.1 through 2.13.5, which should improve the clarity of this section.

Reporting Requirements

AHAM and GE requested clarification on what specific data will be made public with regards to the alternate cycle settings tested in Part (B). (AHAM, No. 34 at p. 7; GE, No. 35 at p. 2) Similarly, ALS requested clarification regarding the requirement for manufacturers to provide a list of all cycle settings comprising the complete energy test cycle for each basic model. ALS requested that DOE make this information publicly available to all interested parties. (ALS, No. 32 at p. 1).

DOE does not intend to make the list of all cycle settings comprising the energy test cycle for each clothes washer publicly available as part of a manufacturer's certification report. DOE will respond to requests for this information pursuant to its Freedom of Information Act regulations at 10 CFR part 1004. DOE acknowledges that making this list publicly available could reveal a manufacturer's proprietary strategies for achieving a competitive advantage over its rivals. In addition, the information could be used to reverse-engineer the products or test results of competitors. Irrespective of requests from the public for this information, DOE notes that it may make this information available to third party laboratories that would be involved in future DOE-initiated compliance verification and enforcement testing.

Today's final rule modifies the reporting requirements in 10 CFR 429.20 by specifying that a certification report shall include publicly available information including MEF, WF, and capacity. The report would also include the list of cycle settings comprising the complete energy test cycle for each basic model, which DOE does not intend to make publicly available as part of the report. The requirement to provide the list of cycle settings comprising the complete energy test cycle will apply only to test results obtained using appendix J2.

5. Capacity Measurement Method

The test procedure in appendix J1 requires measuring clothes container capacity as ''the entire volume which a dry clothes load could occupy within the clothes container during washer operation.'' The procedure involves filling the clothes container with water, and determining the volume based on the weight of the added water divided by its density. Specifically, the test procedure requires that the clothes container be filled manually with either 60 °F ± 5 °F (15.6 °C ± 2.8 °C) or 100 °F ± 10 °F (37.8 °C ± 5.5 °C) water to its ''uppermost edge.''

DOE recognized that this specification of the water fill level could lead to multiple interpretations and, in some cases, capacity measurements that may not reflect the actual volume in which cleaning performance of the clothes could be maintained. After considering comments from interested parties on a proposed interpretation of the existing methodology in appendix J1, DOE issued guidance on identifying the maximum fill level using the appendix J1 test procedure. This guidance, issued on July 26, 2010, is available at *http://www1.eere.energy.gov/buildings/appliance_standards/residential/pdfs/cw_guidance_faq.pdf*, hereafter referred to as the ''capacity guidance.'' Figure III.1 and Figure III.2 show the schematics presented in the capacity guidance, which indicate possible interpretations of the maximum fill level in appendix J1.

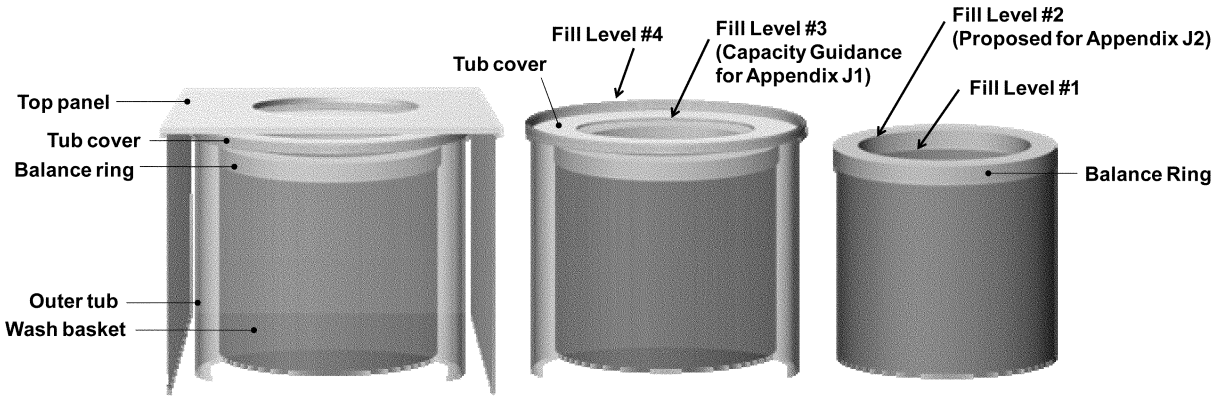

Figure III.1 Representation of Fill Levels for the Clothes Container Capacity Measurement for Vertical-Axis (Top-Loading) Clothes Washers

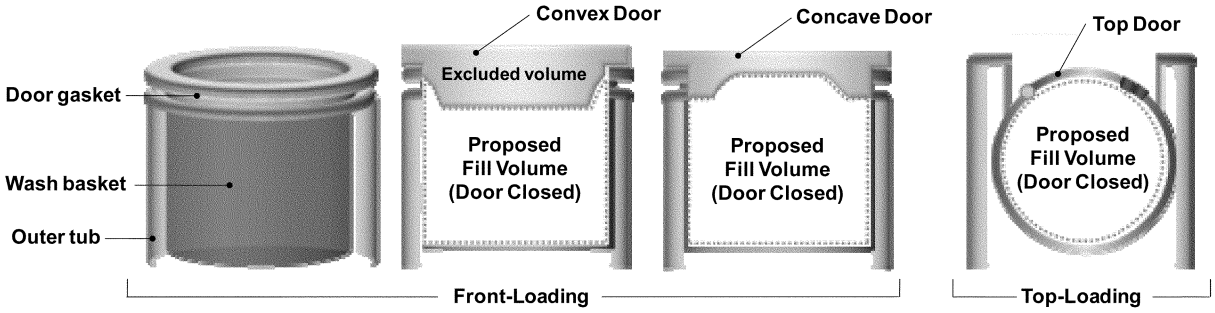

Figure III.2 Representation of Fill Volumes for the Clothes Container Capacity Measurement for Horizontal-Axis (Front-Loading and Top-Loading) Clothes Washers[11]

Figure III.1 indicates four possible fill levels for vertical axis (top-loading) clothes washers:

- ''Fill Level 1'' represents the level immediately below the bottom edge of the balance ring, which typically corresponds to the recommended maximum fill level according to manufacturer instructions.
- ''Fill Level 2'' represents the uppermost edge of the rotating portion of the wash basket, which corresponds to the fill level proposed in the September 2010 NOPR.
- ''Fill Level 3'' represents the highest point of the inner-most diameter of the tub cover.
- ''Fill Level 4'' represents the highest edge on the tub cover.

For the purpose of issuing guidance, DOE determined that the maximum fill level referred to in the appendix J1 test procedure (*i.e.,* the ''uppermost edge'') is the highest horizontal plane that a dry clothes load could occupy with the clothes container oriented vertically. For top-loading clothes washers, this is identified as Fill Level 3 in Figure III.1.

In Figure III.2, the volumes contained within the dotted lines indicate the fill volumes for horizontal-axis (both front-loading and top-loading) clothes washers with convex doors, concave doors, or top-loading doors.

DOE considered whether to amend the fill level specification in this rulemaking to provide additional clarity and ensure that the capacity is representative of the volume available to achieve real-world cleaning performance. Prior to publication of the September 2010 NOPR, DOE conducted capacity tests on a sample of residential clothes washers to observe how different interpretations of the maximum fill level could lead to different measured capacities for the same machine. For top-loading clothes washers, DOE's test sample showed that the majority of rated capacity values varied from the Fill Level 3 value, some by as much as 0.5 ft^3. For front-loading clothes washers, the majority of rated capacity values closely corresponded to DOE's measured values according to the fill volume shown in the capacity guidance.

DOE also tentatively concluded for top-loading clothes washers that Fill Level 3, which was specified in the capacity guidance, may not reflect the actual usable capacity for washing a load of clothes while maintaining cleaning performance. This is because Fill Level 3 may include space above the upper surface of the rotating wash tub or balance ring. In most cases, if

[1] DOE is aware of at least one top-loading, horizontal-axis clothes washer on the market. Based on its geometry, the capacity guidance for this type of clothes washer would be the same as the guidance for front-loading, horizontal-axis clothes washers.

clothes were located in that region during a wash cycle, that portion of the load would likely not interact with water and detergent properly, particularly since wash water cannot be contained between Fill Level 2 and Fill Level 3 during operation. Entanglement of the clothing could also occur.

Therefore, in the September 2010 NOPR, DOE proposed the following fill levels to provide for a more representative capacity measurement:

- For top-loading clothes washers, DOE proposed that the clothes container be filled to the uppermost edge of the rotating portion, including any balance ring. This corresponds to Fill Level 2 in Figure III.1.
- For front-loading clothes washers, DOE proposed that the clothes container be filled to the uppermost edge that is in contact with the door seal.

For both top-loading and front-loading clothes washers, any volume within the clothes container that a clothing load could not occupy during active washing mode operation would be excluded from the measurement.

BSH, the California Utilities, the Joint Commenters, and NEEA support the proposal for measuring the volume of the clothes container. BSH stated that if clothing should not occupy an area, that volume should be excluded from the clothes container capacity measurement. According to BSH, if an area not occupied by clothing were to be measured, top-loading washers would have an unfair advantage over front-loading washers, which have no such area. According to BSH, due to the space needed for agitation, the volume of the clothes container can be larger in top-loading washers, yet offer the consumer a smaller available space to load clothing. (BSH, No. 17 at p. 4) The California Utilities and NEEA agree that the capacity measurement should include the entire volume that a dry clothes load could occupy within the clothes container during washer operation. NEEA stated that this method is an improvement over the previous guidance and will result in consistent, accurate measurements for all clothes washer models. (California Utilities, No. 18 at pp. 4–5; NEEA, No. 12 at p. 13; NEEA, Public Meeting Transcript, No. 20 at p. 177) The Joint Commenters stated that the proposed methodology would ensure that only the space that is capable of being filled with clothes while maintaining proper wash performance is included in the capacity measurement. (Joint Commenters, No. 16 at p. 8).

AHAM, ALS, and Whirlpool oppose the proposed clothes container capacity measurement. AHAM stated that the proposed methodology is ambiguous and does not provide for a representative, repeatable, or reproducible measurement of clothes container volume. AHAM stated that DOE appears to be applying a new interpretation to an existing definition, as there is no change in the definition of the clothes container from the existing appendix J1 to the proposed appendix J2. According to AHAM, there is significant harm in DOE continuing to change its position on the capacity measurement procedure, as it results in a lack of clarity and certainty to the industry, which in turn creates confusion for consumers since machines need to be re-tested and potentially re-rated (and thus, re-labeled) each time the capacity measurement changes. AHAM further commented that the cost associated with re-testing, re-rating, and re-labeling is significant. (AHAM, No. 14 at p. 14) AHAM proposes that DOE codify the final capacity guidance on clothes container capacity measurement without change. AHAM and Whirlpool noted that a significant amount of work on the part of DOE and stakeholders went into the capacity guidance, and the result was a clear, repeatable, reproducible method for measuring drum volume. AHAM and Whirlpool also stated that the capacity guidance addresses the objective that the clothing remain within the clothes container for an entire operating cycle, noting that filling the clothes container slightly above the balance ring with dry clothing will cause the clothing to remain in the clothes container during the entire operating cycle, because clothes sink as they are wetted. (AHAM, No. 14 at pp. 14–15; AHAM, Public Meeting Transcript, No. 20 at pp. 165–167; Whirlpool, No. 13 at p. 12; Whirlpool, Public Meeting Transcript, No. 20 at pp. 167–168, 173–174) Whirlpool stated that its field use studies have shown that customers load the clothes container above the fill level specified in the capacity guidance, and that the maximum load size specified in the DOE test procedure, when loosely loaded, exceeds that fill level. Whirlpool further noted that the Underwriters Laboratories (UL) safety test limit for clothes washers is an even higher fill level. Whirlpool commented that measurements at the fill level specified in the capacity guidance can be as repeatable and reproducible as the proposed fill level. Whirlpool suggested that if DOE questions repeatability and reproducibility, it could require manufacturers to mold a mark at the point on the tub cover at which the clothes container capacity measurement is taken. (Whirlpool, No. 13 at p. 12) ALS opposes the proposed clothes container capacity measurement, stating that manufacturers have based their designs on DOE's capacity guidance for appendix J1. According to ALS, top-loading clothes washers would be rated as having a lower capacity under DOE's proposal because ''the uppermost edge of the rotating portion'' is typically below the fill level defined in the capacity guidance. (ALS, No. 10 at p. 4).

DOE believes that the procedure for measuring clothes washer capacity should reflect the actual usable capacity for washing clothes while maintaining cleaning performance. For front-loading clothes washers, interested parties generally support the proposed methodology for measuring clothes container capacity. For top-loading clothes washers, DOE acknowledges the effort that went into developing the capacity guidance for the current appendix J1 test procedure. DOE believes that, given the construct of the capacity measurement procedure in appendix J1, the capacity guidance provides improved clarity, repeatability, and reproducibility to the current test procedure. For this rulemaking, however, DOE re-evaluated all aspects of the clothes container capacity measurement and concluded that the capacity measurement specified in appendix J2 maximizes clarity, repeatability, reproducibility, and consumer relevance.

First, while DOE did not change the definition of ''clothes container'', the upper boundary of the ''clothes container'' is not explicitly defined in the current clothes washer test procedure at appendix J1. Section 3.1 of appendix J1 requires the measurement of ''the entire volume which a dry clothes load could occupy within the clothes container during washer operation.'' DOE did not propose to change the language in section 3.1 for appendix J2 in the September 2010 NOPR. After considering comments on the related proposal to amend the fill level in section 3.1.4, however, DOE acknowledges that a volume of dry clothing may not correspond to the same volume of wet clothing in a clothes washer, because loosely packed clothing often compacts once it becomes wet. The maximum volume of a dry clothing load could vary considerably based on the density, stiffness, absorption, and other properties of the material composition. Therefore, DOE concludes that it is not meaningful to base the capacity measurement on the volume that dry clothes could occupy. Instead, the revised capacity measurement provisions in today's final

rule, particularly those for top-loading clothes washers, more appropriately represent the actual usable volume of the clothes container during the active mode portion of washer operation. Today's final rule provides revised language in section 3.1 of appendix J2 that removes the qualification that the clothes load be dry, and instead specifies that the clothes load could occupy the volume during ''active mode washer operation.''

In determining the appropriate fill level for the capacity measurement, DOE notes that the current capacity guidance is accompanied by a set of diagrams illustrating Fill Level 3 for a variety of top-loading clothes washer tub cover designs. DOE has, however, observed significant variation in tub cover designs among products from different manufacturers, as well as within individual manufacturers' product lines, and DOE continues to receive requests for clarification on tub cover shapes not included in the diagrams. In addition, DOE has observed some tub covers with varying heights around the inner-most diameter, and in these cases, the ''highest point of the inner-most diameter'' may not be the most appropriate fill height. For these machines, determining the maximum fill level can require the subjective judgment of the test laboratory. DOE's testing indicates that Fill Level 2, as proposed in the September 2010 NOPR and defined as ''the uppermost edge of the rotating portion, including any balance ring,'' provides a much clearer reference point. DOE has observed significantly less variation in balance ring designs among manufacturers compared to tub cover designs. For these reasons, DOE has determined that Fill Level 2 offers greater clarity than Fill Level 3, which would also result in greater repeatability and reproducibility.

DOE also believes that the proposed Fill Level 2 is more consumer-relevant than Fill Level 3. DOE acknowledges that if a consumer loaded a top-loading machine with clothing as high as Fill Level 3 (or higher), the clothing would likely sink to a lower level within the clothes container as the load is wetted. DOE has observed, however, that virtually all of the clothes washer user manuals it reviewed direct the consumer to load clothing no higher than the highest drain holes in the wash basket, which typically corresponds to the point at which the wash basket meets the lower edge of the balance ring (corresponding to Fill Level 1 in Figure III.1). DOE believes that, by respecting manufacturer recommendations, Fill Level 1 would best ensure wash performance is maintained, and thus is the most consumer-relevant. DOE further believes that should clothing occupy the space between Fill Level 1 and Fill Level 2 during a wash cycle, the clothing could be cleaned sufficiently because water can still be contained within that volume. Clothing above Fill Level 2, however, is not likely to be cleaned sufficiently because it would be outside the wash basket during the wash cycle. Additionally, clothing that occupies space above Fill Level 2 risks being damaged if it becomes entangled on stationary fixtures such as the tub cover or other mechanical components of the washer during the wash cycle.

Furthermore, certain design changes to the shape of the inner diameter of the tub cover (Fill Level 3) can be incorporated that would result in an increase of the measured capacity with no corresponding increase in real-world usable capacity, because wash water cannot be contained between Fill Level 2 and Fill Level 3. Increasing the height of the balance ring (Fill Level 2), however, would correspond to a real increase in usable capacity from the consumer's perspective, since the wash water could be contained up to the top of the balance ring.

For these reasons, today's final rule adopts the clothes container capacity measurement provisions for top-loading clothes washers as proposed in the September 2010 NOPR. The change will be incorporated into appendix J2, which will not need to be used to demonstrate compliance until the compliance date of any amended standards for these products.

Whirlpool stated that, to achieve parity between top-loading and front-loading machines using the proposed clothes container capacity measurement, the test procedure when applied to front-loading clothes washers must (1) require removal of the bellows prior to measurement; and (2) require that the shipping bolts remain in place, as was specified in the capacity guidance, to prevent sagging of the basket when the machine is tipped on its back. (Whirlpool, No. 13 at p. 13; Whirlpool, Public Meeting Transcript, No. 20 at pp. 178–180) BSH stated that the definition of shipping bolts is not clear. (BSH, Public Meeting Transcript, No. 20 at p. 179).

For front-loading clothes washers, DOE agrees that the shipping bolts should remain in place during the capacity measurement to prevent the clothes container from sagging downward when filled with water, which would stretch the door gasket (also referred to as the bellows), creating additional volume that the clothes load could not occupy during actual washer operation. Downward sagging could also cause damage to the clothes container structure during the test. DOE has also determined that the gasket should remain in place for the capacity measurement, because some portion of the gasket may occupy the volume available for the clothes load when the door is closed, and this volume should be excluded from the measured capacity. For these reasons, today's final rule adds to the provisions proposed in the September 2010 NOPR by specifying that the shipping bolts and door gasket shall remain in place during the capacity measurement for front-loading clothes washers.

AHAM, the California Utilities, LG, NRDC, and Springboard commented that DOE should add diagrams to the test procedure for clarity in interpreting the clothes container capacity measurement, similar to what was provided in the capacity guidance. LG further stated that the diagram for top-loading clothes washers should label the balance ring to indicate the fill level. (AHAM, Public Meeting Transcript, No. 20 at pp. 174–175; California Utilities, No. 18 at pp. 4–5; LG, Public Meeting Transcript, No. 20 at pp. 177–178; NRDC, Public Meeting Transcript, No. 20 at p. 175; Springboard, No. 11 at p. 1) NRDC requested clarification as to whether the clothes container capacity for front-loading clothes washers should be measured with the door opened or closed. (NRDC, Public Meeting Transcript, No. 20 at pp. 161–165).

DOE has observed a broad range of designs and configurations of the key components of the clothes container among products already available on the market, and expects that other designs could be introduced in future clothes washers. DOE will continue to publish the fill level diagrams, updated as necessary for new designs, on its Web site at *http://www1.eere.energy.gov/buildings/appliance_standards/residential/clothes_washers.html*.

6. Test Cloth, Detergent, and Preconditioning Test Equipment

Multiple interested parties submitted comments regarding the use of test cloth in response to the August 2009 standards framework document. Based on these comments, DOE proposed in the September 2010 NOPR a number of amendments related to test cloth, detergent, and other preconditioning test equipment.

DOE received multiple comments that generally responded to DOE's proposed test cloth provisions. AHAM submitted recommendations for test cloth specifications, and commented that DOE should incorporate them to

improve reproducibility. (AHAM, No. 2 at p. 23; AHAM, No. 14 at p. 14) Some of AHAM's comments reflect the recommendations of the AHAM Energy Test Cloth Task Force, which was formed in February 2008 to identify and address appliance manufacturers' concerns pertaining to Lot 15 test cloth. The specific objectives of the AHAM Energy Test Cloth Task Force were to investigate test cloth consistency and RMC measurement process variation. The Task Force is comprised of BSH, Electrolux, General Electric, Samsung, Whirlpool Corporation, and SDL Atlas. (AHAM, No. 4 at p. 4) ALS stated that it supports AHAM's test cloth proposal. (ALS, No. 10 at p. 4) NEEA commented that the proposed test cloth procedures and specifications are reasonable. (NEEA, No. 12 at p. 13) Whirlpool supports the proposed test cloth changes with additional recommendations for extractor testing. (Whirlpool, No. 13 at p. 11–12) The sections below provide additional details regarding each proposed amendment related to the test cloth, as well as responses to comments on specific test cloth provisions proposed in the September 2010 NOPR and August 2011 SNOPR.

Test Cloth Definitions

In response to the September 2010 NOPR, AHAM commented that a test cloth ''lot'' should be defined as ''a quantity of cloth that has been manufactured with the same batches of cotton and polyester during one continuous process. The cotton and polyester for each lot can come from only one supplier. The supplier is responsible for manufacturing the raw materials consistently to ensure uniformity.'' AHAM also recommended that ''roll'' be defined as ''a subset of a lot.'' AHAM stated that a requirement should be added to section 2.6.1 that all energy test cloth must be permanently marked, identifying the roll number as well as lot number of the material, and that in section 2.6.5.2, ''[t]est loads shall be comprised of randomly selected cloth at the beginning, middle, and end of a lot.'' AHAM commented that the test procedure should contain test cloth quality control provisions for identifying the roll number and evaluating the consistency of the lot by means of an advisory board, which would approve the lot of test cloth prior to sale, ensuring that the coefficient of variation from the average RMC value from each roll would be less than 1 percent. According to AHAM, the advisory board would consist of a representative from DOE, AHAM, each automatic washer appliance manufacturer, and test cloth supplier, and that the board's purpose would be to review and approve each new test cloth lot, new cloth suppliers, and correction factor test facilities. (AHAM, No. 4 at p. 4; AHAM, No. 14 at pp. 14, 19–20, 23, 26, 28)

DOE's test procedure is intended to define material properties of the test cloth sufficiently narrowly as to ensure accuracy and repeatability of the test procedure, and provide procedures to normalize test results to account for allowable variations in the test cloth properties. DOE notes that a supplier may elect to provide additional identifying information, including roll number, on the test cloth as it deems appropriate. DOE agrees with AHAM that definitions of ''lot'' and ''roll'' would clarify the existing provisions regarding the energy test cloth, and is adopting in today's final rule the definition of lot as ''a quantity of cloth that has been manufactured with the same batches of cotton and polyester during one continuous process.'' The specification of ''same batches of cotton and polyester during one continuous process'' essentially requires these raw materials to come from a single supplier; therefore, DOE is not including such a qualification in the definition. DOE is also adopting in today's final rule the definition of ''roll'' as ''a subset of a lot.''

Energy Test Cloth Size and Weight Tolerances

The existing clothes washer test procedure does not specify any tolerances for the size and weight of the energy test cloths. In the September 2010 NOPR, DOE proposed the following tolerances for the test cloth:

- In section 2.6.1, ''Energy Test Cloth,'' the energy test cloth shall be 24 ± ½ inches by 36 ± ½ inches (61.0 ± 1.3 cm by 91.4 ± 1.3 cm) and hemmed to 22 ± ½ inches by 34 ± ½ inches (55.9 ± 1.3 cm by 86.4 ± 1.3 cm) before washing;
- In section 2.6.2, ''Energy Stuffer Cloth,'' the energy stuffer cloth shall be 12 ± ¼ inches by 12 ± ¼ inches (30.5 ± .6 cm by 30.5 ± .6 cm) and hemmed to 10 ± ¼ inches by 10 ± ¼ inches (25.4 ± .6 cm by 25.4 ± 0.6 cm) before washing; and
- In section 2.6.4.2, the fabric weight specification shall be 5.60 ± 0.25 ounces per square yard (190.0 ± 8.4 g/m^2).

In addition, DOE proposed to create a new specification for maximum shrinkage in section 2.6.4.7 based on the American Association of Textile Chemists and Colorists (AATCC) Test Method 135–2004. DOE proposed to increase the previous shrinkage limit from four percent to five percent. In the August 2011 SNOPR, DOE proposed using the most recent version of this standard, AATCC Test Method 135–2010.

AHAM commented that the test cloth dimensional properties should be refined to match supplier capability, including length, width, fabric weight, and shrinkage properties. (AHAM, No. 4 at p. 4) DOE notes that the size tolerances and test cloth weight proposed in the September 2010 NOPR are identical to those in AHAM's proposed changes to the DOE clothes washer test procedure, which AHAM included as part of its written comment. AHAM noted in the written comment that these specifications were supported by supplier data, and thus DOE is adopting the proposed test cloth dimensions and weight in today's final rule.

AHAM supports DOE's proposal to add the newly referenced AATCC Test Method 135 for measuring shrinkage of the energy test cloth, and supports increasing the shrinkage limit from four percent to five percent. Today's final rule specifies a maximum shrinkage limit of five percent, to be measured using AATCC Test Method 135–2010. (AHAM, No., 14 at p. 16; AHAM, No. 24 at p. 5).

Detergent Specification and Dosage

In the September 2010 NOPR, DOE proposed amending the clothes washer test procedure to specify the use of the AHAM standard test detergent Formula 3 in test cloth preconditioning, at a dosing of 27.0 g + 4.0 g/lb.

ALS supported DOE's proposal to specify the use of AHAM standard detergent Formula 3 in test cloth preconditioning as well as the proposal to follow the instructions included with the detergent, because it makes the dosing identical to that of the dryer test load preconditioning procedure. (ALS, No. 10 at p. 5) NEEA stated that it foresees no problem with, and some benefit from, adopting the AHAM detergent specification. (NEEA, No. 12 at p. 14) Whirlpool stated that the proposed detergent formulation and dosage changes are consistent with AHAM Standard HLD–1–2009, which Whirlpool supports. (Whirlpool, No. 13 at p. 14; Whirlpool, No. 27 at p. 4) AHAM supported DOE's proposal to amend the test procedure to specify the use of AHAM standard test detergent Formula 3 in test cloth preconditioning at a dosing of 27.0 g + 4.0 g/lb (AHAM, No. 14 at p. 15; AHAM, Public Meeting Transcript, No. 20 at pp. 194–195; AHAM, No. 24 at p. 6).

For the reasons stated above and in the September 2010 NOPR, today's final rule specifies the use of AHAM standard

test detergent Formula 3 in test cloth preconditioning, at a dosing of 27.0 g + 4.0 g/lb, in both appendix J1 and the new appendix J2.

Test Cloth Preconditioning Wash Requirements

Section 2.6.3.1 of the current DOE clothes washer test procedure specifies preconditioning the test cloths using a clothes washer in which the load can be washed for 10 minutes at the maximum water level and a wash temperature of 135 °F ± 5 °F (57.2 °C ± 2.8 °C).

DOE noted in the September 2010 NOPR that multiple manufacturers expressed concern during manufacturer interviews that there are currently few clothes washers commercially available that meet these requirements. The manufacturers also expressed concern that the more stringent energy conservation standards that may result from the residential clothes washer standards rulemaking may eliminate such clothes washer models from the market entirely. DOE did not propose any updates to the preconditioning clothes washer specifications in the September 2010 NOPR, but sought information regarding an alternative specification for the clothes washer to be used for preconditioning that would allow for the use of more recent models.

DOE received the following information and comments from interested parties regarding the clothes washer requirements for test cloth preconditioning.

ALS stated that clothes washers will be available after the next DOE minimum efficiency standards for clothes washers take effect that can adequately precondition the test cloth. ALS believes there is adequate time to learn of any differences that may occur with new clothes washer designs. Furthermore, ALS suggested that manufacturers and certification test labs could purchase and maintain inventory of the current design of agitator-style, vertical-axis clothes washers that ALS manufactures. (ALS, No. 10 at p. 5).

Whirlpool stated that top-loading clothes washers with a deep-fill rinse option will continue to be available for quite some time. Agitator-based models may no longer be viable at some point in the future, but impeller-based models should be available. (Whirlpool, No. 13 at p. 14).

AHAM stated that the key attributes for the clothes washer used for preconditioning are that it be able to achieve good rinsing and be able to get the test cloth to its final size. AHAM stated that there will be clothes washers capable of good rinsing and getting the test cloth to its final size at least through year 2018. AHAM stated that manufacturers may need to select a fabric softener cycle to achieve those goals, for example, but the goals are workable with current machines. (AHAM, No. 14 at p. 16).

BSH commented that it does not foresee any problems meeting the test cloth pre-conditioning method outlined by DOE. The method asks for maximum water level and a fixed temperature for wash and rinse water. BSH stated that it can internally create a clothes washer that meets the specified temperatures. BSH added that since maximum water level is not defined as a specific quantity, using the maximum water level for washing in BSH clothes washers would meet the standard. (BSH, No. 17 at p. 5; BSH, Public Meeting Transcript, No. 20 at p. 198–199) BSH commented further that it does not want to see one specific product model specified for pre-conditioning, as this would limit the ability to keep current equipment in laboratories. As the model is replaced in the market by its manufacturer, access and ability to test would be affected in all laboratories. BSH supports AHAM's comment that the primary goals are to achieve good rinsing and assure that the cloth reaches its final size before testing. (BSH, No. 17 at p. 5) As an alternative, BSH would support the IEC test cloth pre-conditioning method if the Department believes it to be appropriate. (BSH, No. 17 at p. 5).

NEEA commented that participants at the October 2010 public meeting generally agreed that the clothes washer characteristics specified for test cloth preconditioning may no longer be available, or will soon be unavailable. According to NEEA, it was not made clear by manufacturers at the meeting exactly which characteristics were a problem, *i.e.,* relatively high water temperature, a ten minute wash, or the ability to specify the water level. NEEA believes the best course of action would be to provide the rationale for the current specifications, and then propose an alternative set of clothes washer specifications that manufacturers could assure DOE will be commonly available, yet would result in preconditioning performance that closely approximates that of the current specification. (NEEA, No. 12 at p. 14; NEEA, Public Meeting Transcript, No. 20 at pp. 200–201).

DOE's intended goals for the test cloth preconditioning are to remove any chemical residues or other finishes that may be present on the surface of the test cloth and to subject each test cloth to a series of wash/rinse/dry cycles to induce any shrinking that may occur, so that each test cloth achieves its final size before being used for testing. Achieving these goals requires the use of detergent, an adequate quantity of hot water for the wash and cold water for the rinse, and a minimum temperature in the preconditioning dryer.

In consideration of comments from interested parties, DOE expects that clothes washers capable of meeting the test cloth preconditioning requirements will continue to be available after the revised energy efficiency standards for clothes washer become effective. Based on the recommendations provided by AHAM, DOE amends the test cloth preconditioning requirements to specify that a minimum of 20 gallons of water be used in each wash/rinse/spin cycle during test cloth preconditioning. However, DOE is not otherwise changing the preconditioning requirements of section 2.6.3.1.

AATCC Test Methods

Section 2.6.4.5.3 of the existing test procedure incorporates by reference standards for verifying the absence of water repellent finishes on the energy test cloth: AATCC Test Method 118–1997, ''Oil Repellency: Hydrocarbon Resistance Test'' and AATCC Test Method 79–2000, ''Absorbency of Textiles.'' To be consistent with referenced standards in other DOE test procedures, DOE proposed in the September 2010 NOPR to remove this paragraph from the clothes washer test procedure and, instead, include these two AATCC test procedures in 10 CFR part 430.3, ''Materials Incorporated by Reference.'' In addition, DOE proposed adding to 10 CFR part 430.3 the newly-referenced AATCC Test Method 135–2004, ''Dimensional Changes of Fabrics after Home Laundering'' for measuring shrinkage of the energy test cloth, which is referenced in section 2.6.4.7 of the revised test procedure.

AHAM supports DOE's proposal to move the reference to standards incorporated by reference from the test procedure in appendix J1 to the regulatory text at 10 CFR 430.3. The reference will also be applicable to appendix J2. (AHAM, No. 14 at p. 16)

For the reasons stated above and in the September 2010 SNOPR, today's final rule implements the changes proposed in the September 2010 NOPR, as described above. Today's final rule also corrects a typographical error from the November 2011 SNOPR in the mailing address for AATCC. The correct address is P.O. Box 12215. Today's final rule also updates the contact telephone number to (919) 549–3526, which is listed on the cover page of the current versions of the AATCC standards.

Required Extractor Tests

The current DOE test procedure uses extractor tests of up to 500 units of gravitational acceleration (g, or g-force) in determining the RMC correlation curve for test cloth lots. DOE is aware of clothes washers currently available on the market capable of reaching g-forces higher than 500 g.

DOE therefore proposed in the September 2010 NOPR to include an additional set of extraction tests at 650 g. Because of the prevalence of higher spin speeds in clothes washers available on the market, DOE also proposed to remove the requirement that the 500 g condition be required only if a clothes washer can achieve spin speeds in the 500 g range. These proposed amendments would result in 60 extractor RMC test runs being required for correlation testing rather than the currently-required 48. DOE also proposed to update Table 2.6.5—Matrix of Extractor RMC Test Conditions, and Table 2.6.6.1—Standard RMC Values (RMC Standard) in the test procedure to include tests at 650 g. The proposed updated Table 2.6.6.1 is shown below as Table III.5, and it contains the additional standard RMC values at 650 g that were suggested by AHAM and supported by the AHAM Energy Test Cloth Task Force.

TABLE III.5—STANDARD RMC VALUES (RMC STANDARD)—PROPOSED IN SEPTEMBER 2010 NOPR

"g Force"	RMC percentage			
	Warm soak		Cold soak	
	15 min. spin	4 min. spin	15 min. spin	4 min. spin
100	45.9	49.9	49.7	52.8
200	35.7	40.4	37.9	43.1
350	29.6	33.1	30.7	35.8
500	24.2	28.7	25.5	30.0
650	23.0	26.4	24.1	28.0

In response to the September 2010 NOPR, AHAM reiterated its recommendation to require the 500 g condition for all test cloth lots and to add a 650 g condition to the extractor RMC test runs to reflect higher spin speeds in current clothes washers. AHAM also supported the standard RMC values proposed for each of these extraction conditions. (AHAM, No. 4 at p. 4; AHAM, No. 14 at pp. 26–28).

Today's final rule is consistent with the September 2010 NOPR. It requires the 500 g extraction for all test cloth lots and adds a 650 g extraction test in Table 2.6.5 and Table 2.6.6.1 of the revised test procedure.

Extractor Specification

In the September 2010 NOPR, DOE proposed to update the manufacturer specified for the extractor from Bock Engineered Products to North Star Engineered Products, Inc. DOE also noted that North Star Engineered Products, Inc. operates at the same location and supplies the same model of extractor as the previously specified Bock Engineered Products.

AHAM and Whirlpool agreed that the standard extractor RMC tests should be run in a North Star Engineered Products, Inc. (formerly Bock) Model 215 extractor, but added that the basket diameter should be 20 inches and the basket height should be 11.5 inches. (AHAM, No. 14 at p. 26; Whirlpool, No. 13 at p. 11) AHAM and Whirlpool stated that the extractor should be calibrated to meet the acceleration profiles shown in Table III.6 (AHAM, No. 14 at p. 26; Whirlpool, No. 13 at p. 11):

TABLE III.6—AHAM AND WHIRLPOOL-RECOMMENDED EXTRACTOR CALIBRATION

RPM	"g" Force	RPM/S (spin-up acceleration)
594 ± 5	100	46 ± 3
840 ± 5	200	42 ± 3
1111 ± 5	350	38 ± 3
1328 ± 5	500	36 ± 3
1514 ± 5	650	35 ± 3

AHAM and Whirlpool stated that the timers for different extractors made by the same manufacturer start measuring time at different conditions; *i.e.,* they may start timing immediately when the extractor starts or they may start timing only when the requested spin speed is attained. AHAM and Whirlpool requested that DOE clarify the start time for extractor tests. (AHAM, No. 14 at p. 26; Whirlpool, No. 13 at p. 11).

DOE concurs with AHAM and Whirlpool that the extractor model and basket dimensions should be updated to accurately describe the North Star Engineered Products Inc., (formerly Bock) Model 215 extractor.

Regarding AHAM and Whirlpool's suggested extractor calibration, DOE agrees that the nominal revolutions per minute (RPM) listed in Table III.6 will produce the desired g-force levels for a 20-inch diameter basket. However, DOE's analysis indicates that specifying an allowable range of ±5 RPM would result in too large of a deviation from the specified g-force. Section 2.6.5.3.3 in the current test procedure allows a ±1 g deviation from the intended centripetal acceleration level for each extractor test, and today's final rule maintains this tolerance in the amended test procedure. DOE notes that for an extractor basket with a 20-inch diameter, a deviation of ±5 RPM at the 100 g-force level would result in a ± 2 g deviation in g-force level; (i.e., a spin speed of 599 RPM—instead of the nominal 595 RPM—would result in 102 g-force). Likewise, a deviation of ±5 RPM at the 650 g-force level would result in a ±4 g deviation in g-force level. Therefore, today's final rule specifies an allowable range of ±1 RPM for the extractor spin speed. This will ensure that the maximum ±1 g deviation from the intended g-force level will be maintained for each spin speed. Based on DOE's internal extractor testing, DOE has observed that the North Star Model 215 extractor is capable of maintaining the spin speeds within ±1 RPM.

AHAM and Whirlpool also suggested specifying the allowable spin-up time for each test, implicitly determined by the acceleration noted in the column labeled RPM/S in Table III.6. This suggestion was coupled with another to start the extractor and the test timer simultaneously. However, DOE has observed that the user is unable to adjust the spin-up time on the North Star Model 215 extractor, and therefore, specifying the spin-up time in the test procedure could provide too rigid of a constraint. Additionally, because the amount of water extracted depends primarily on the g-force exerted on the test cloth, and because the g-force varies as a function of the square of RPM, the

period of time spent at full spin speed will affect the amount of water extracted much more than the time spent during the extractor spin-up and spin-down periods. Therefore, DOE believes that specifying the time spent at full spin speed is more important than specifying a total test time that would include the spin-up and spin-down time. For these reasons, today's final rule specifies that the timer shall begin when the extractor reaches the full required spin speed, but does not specify an allowable spin-up time for each test. DOE believes that this approach will provide the most consistent, repeatable test results among all laboratories. DOE is aware that the timer and control system on the North Star Model 215 extractor can be upgraded, if necessary, so that the timer automatically starts when the extractor reaches full speed.

Bone Dryer Specifications

In the September 2010 NOPR, DOE proposed to update the requirements for bone drying the test cloth in preparation for determining the RMC of the test loads in the extractor tests. The proposal included a requirement in section 2.12 for using a clothes dryer capable of heating the test cloth to above 210 °F (99 °C).

AHAM and Whirlpool suggested clarifications to the methodology for the bone drying procedure used before each extractor test run. According to AHAM, the procedure would state, ''Place dry load in a dryer and dry for 10 to 40 minutes depending on the load size. Remove and weigh before cool down. Continue drying for 10 minute periods until the weight change is 1% or less.'' AHAM and Whirlpool commented that the dryer performance requirements should state, ''Dryer used for bone drying must heat cloth above 210 deg F (99 deg C).'' AHAM added the recommendation to ''[r]ecord the end of cycle bone dry test cloth temperature at the end of the cycle.'' (AHAM, No. 14 at p. 26; Whirlpool, No. 13 at p. 11).

Based on AHAM and Whirlpool's comments in support of DOE's proposal, today's final rule adds a requirement that the dryer used for bone drying must heat the test cloth above 210 °F (99 °C). DOE determined that specifying the duration and methodology of the bone drying procedure to be used during the extractor tests, as AHAM suggested, would be redundant because the definition of ''bone-dry'' already includes this information. Today's final rule specifies the bone drying methodology to be used during the extractor tests by referring to the definition of ''bone-dry'' in the definitions section of the test procedure, which will achieve the same objective as AHAM's proposal.

Today's final rule does not incorporate AHAM's recommendation to record the bone-dry test cloth temperature at the end of the cycle. DOE believes that this would add additional test burden with little corresponding benefit to the overall results of the test procedure. The temperature measurement of the test cloth at the end of the dryer cycle would need to be performed immediately upon termination of the dryer cycle, before the test cloth could begin to cool down. This could present a logistical challenge depending on the sequence of tests and the number of laboratory technicians performing the tests. In addition, AHAM did not specify a method for measuring the temperature of the test cloths, which would be necessary to ensure accuracy and repeatability. DOE believes that the amended bone dryer temperature specification, combined with the definition of ''bone-dry'' already included in the test procedure definitions section, provide a sufficient level of detail for conducting the test cloth extractor tests.

Procedures for Preparing and Handling Test Cloth Bundles

In the September 2010 NOPR, DOE proposed clarifications to the requirements for bundling and draining the test cloth prior to completing the extractor spin cycles. These clarifications included procedures to create loose bundles of four test cloths each, as well as time limits of 5 seconds for gravity draining the bundles after soaking and 1 minute for overall draining and loading of all bundles into the extractor.

AHAM's comments on the September 2010 NOPR included additional recommended specifications for test cloth preparation. Regarding the soak period for the test cloth prior to extraction testing, AHAM suggested adding the requirement to maintain the temperature ''at all times between the start and end of the soak'' to the water soak temperature requirement currently in section 2.6.5.3.2 of appendix J1. (AHAM, No. 14 at p. 27).

AHAM further provided recommended clarifications for the test cloth used in the extractor tests. According to AHAM, the test load should be comprised of randomly selected cloth at the beginning, middle, and end of a lot, and that it would be acceptable to use two test loads for standard extractor RMC tests, with each load used for half of the total of 60 tests. AHAM commented that a testing constraint is the approximate 25-minute ''soak and load'' time for the test cloth, which results in the standard RMC extractor tests taking a week to complete. AHAM stated that with two loads, one load could be soaking while the other load was spinning. (AHAM, No. 14 at p. 26).

DOE supports AHAM's suggestion to add a requirement to maintain the required temperature at all times between the start and end of the soak, which will help eliminate variability in the extractor test results. Today's final rule incorporates this requirement. DOE also supports AHAM's suggestion that the test loads for the extractor tests be comprised of randomly selected cloth from the beginning, middle and end of a lot. This requirement will provide more consistent results and will reduce variability that could occur as a result of material variations within a single test cloth lot. DOE also concurs that allowing two test loads would significantly reduce the test burden required for performing the standard extractor RMC tests. Therefore, today's final rule allows the use of two test loads for the standard extractor RMC tests.

Based on recommendations from the AHAM Energy Test Cloth Task Force, DOE proposed in the September 2010 NOPR to specify that it not be necessary to dry the test load between extraction runs; however, the bone dry weight would need to be checked after every 12 extraction runs to ensure the bone dry weight is still within tolerance. In response to the September 2010 NOPR, AHAM noted that the first test cloth soak after bone drying absorbs less water. Therefore, AHAM suggested that the test procedure require the test load to be soaked and extracted one time following bone drying, before continuing with the remaining RMC tests. This single post-bone-drying extraction would be run at the speed currently being tested, and would last for four minutes. (AHAM, No. 14 at p. 27).

Based on AHAM's comment that the first test cloth soak after bone drying absorbs less water, DOE agrees that the first soak/extraction cycle after bone drying should not be used as a data point in the standard extractor RMC tests. Therefore, DOE adopts AHAM's suggestion and requires that the test load be soaked and extracted for one time following bone drying before continuing with the remaining RMC tests.

Clarification of the RMC Nomenclature and Application of the RMC Correction Curve

In the September 2010 NOPR, DOE proposed to modify the nomenclature used for RMC values that are intermediates in the calculation of a final RMC. The proposed change clarified that the RMC values used in section 3.8.4 of appendix J1 are the values obtained from either section 3.8.2 or 3.8.3. AHAM supports this modification. (AHAM, No. 14 at p. 16).

Additionally, during DOE's ENERGY STAR testing and verification program [12] in April 2011, test laboratories raised questions regarding the application of the RMC correction factors as described in section 2.6.7 of the current appendix J1 test procedure. Specifically, the test procedure does not explicitly describe how to apply the RMC correction factors in the RMC equations in section 3.8. For example, if the calculated value of RMC_{max} in section 3.8.2.5 is 0.455 (or 45.5%), a laboratory could incorrectly apply the correction factor by applying it to the number 45.5 rather than to the fractional value 0.455, to which it should be applied. In addition, for clothes washers with both cold and warm rinse, or with multiple spin speeds, the test procedure does not instruct whether to apply the RMC correction factors before or after combining the component RMC values in sections 3.8.3.3 or 3.8.4 of appendix J1.

To resolve this ambiguity, DOE clarifies the RMC nomenclature and RMC correction calculations throughout section 3.8 of the revised test procedure. Specifically, DOE explicitly defines the RMC correction equations and clarifies the order in which the RMC corrections should be performed for clothes washers with both cold and warm rinse and/or multiple spin speeds.

DOE has also discovered a typographical error in the formula given in section 2.6.6.1 of the test procedure. That formula and the accompanying text provide the means of deriving the linear least-squares coefficients A and B, which relate the extractor-measured RMC values of section 2.6.5 (RMC_{cloth}) and the standard RMC values in Table 2.6.6.1 ($RMC_{standard}$). Currently in appendix J1, section 2.6.6.1 includes the formula (RMC_{cloth}): $RMC_{standard} \sim A * RMC_{cloth} + B$. However, the notation ''(RMC_{cloth}):'' was incorrectly transcribed from a DOE report cited in the January 2001 standards Final Rule.[13] The correct version of the formula should be $RMC_{standard} \sim A * RMC_{cloth} + B$. Today's final rule corrects this error and clarifies that the $RMC_{standard}$ values are linearly related to the RMC_{cloth} values through the coefficients A and B. This correction and clarification apply to both appendix J1 and appendix J2.

In addition, DOE has observed that the description of the analysis of variance test to be performed in section 2.6.6.2 is not explicit about several key details of the analysis. Currently in appendix J1, section 2.6.6.2 states, ''Perform an analysis of variance test using two factors * * *''. Because an analysis of variance test can be performed in multiple ways, clarification is needed to specify that an analysis of variance ''with replication'' test should be performed. Additionally, the current provisions state, ''The 'P' value in the variance analysis shall be greater than or equal to 0.1.'' Because several different P-values can be determined, clarification is needed to specify that the P-value in question is ''the 'P' value of the F-statistic for interaction between spin speed and lot in the variance analysis.'' Finally, the current provisions of 2.6.6.2 state that '' 'P' is a theoretically based probability of interaction based on an analysis of variance.'' This is technically incorrect; while ''P'' does represent a measure of interaction between spin speed and lot, it does not represent the probability of interaction between the two. DOE makes these corrections and clarifications in today's final rule to both appendix J1 and appendix J2. DOE notes that these corrections and clarifications are for technical accuracy only, and they will not change how these provisions of the test procedure are conducted.

Removal of Redundant Sections

The current test procedure contains redundant sections regarding the test cloth specifications and preconditioning. DOE proposed in the September 2010 NOPR to remove the redundant sections, currently numbered 2.6.1.1–2.6.1.2.4. These sections were made obsolete by the January 2001 standards Final Rule, which added sections 2.6.3 through 2.6.7.2 into appendix J1. However, DOE proposed to maintain the thread count specification from deleted section 2.6.1.1(A), of 65 × 57 per inch (warp × fill), by moving it to section 2.6.4.3.

AHAM and Whirlpool support deleting these obsolete sections and maintaining the thread count specification of 65 × 57 per inch (warp × fill) by moving it to section 2.6.4.3. (AHAM, No. 14, pp. 23–24; AHAM, No. 24 at p. 5; Whirlpool, No. 27 at p.4) Therefore, for the reasons stated in the September 2010 NOPR, DOE incorporates these changes into both appendix J1 and the new appendix J2 test procedure in today's final rule, as proposed in the September 2010 NOPR.

7. Testing Conditions

Water Supply Pressure

Section 2.4 of the current DOE clothes washer test procedure provides the water pressure test conditions, as follows: ''The static water pressure at the hot and cold water inlet connection of the clothes washer shall be maintained at 35 pounds per square inch gauge (psig) ± 2.5 psig (241.3 kPa ± 17.2 kPa) during the test. The static water pressure for a single water inlet connection shall be maintained at the 35 psig ±2.5 psig (241.3 kPa ± 17.2 kPa) during the test. A water pressure gauge shall be installed in both the hot and cold water lines to measure water pressure.''

DOE notes that this description is ambiguous as to whether the nominal 35 psig water pressure is to be set under static (non-flow) conditions and allowed to drop during flow due to the head losses in the line, or whether the 35 psig is to be maintained continuously under all flow conditions during the test.

In the September 2010 NOPR, DOE discussed the test results from a sample of front- and top-loading clothes washers that indicated that water supply pressure can affect water consumption during a wash cycle, and the effect of water supply pressure on total water use can vary depending on the temperature settings selected. For tests at 10, 20, and 35 psig water supply pressure under flow conditions, water consumption varied by 10–30 percent among the different pressure conditions for either hot wash/cold rinse or cold wash/cold rinse cycles.

DOE noted that the test procedures for other residential appliances specify the 35 psig requirement as being applicable under flow conditions. For example, section 2.4 of the DOE test procedure for dishwashers (10 CFR part 430 subpart B, appendix C) specifies to ''maintain the pressure of the water supply at 35 ± 2.5 pounds per square inch gauge (psig) when the water is flowing.'' Dishwashers and clothes washers would likely have the same water supply pressure when installed in a house, so

[12] Details about DOE's ENERGY STAR testing and verification program available at *http://www1.eere.energy.gov/buildings/appliance_standards/energy_star_testing_verification.html.*

[13] The January 2001 standards Final Rule cited a DOE report titled, ''Development of a Standardized Energy Test Cloth for Measuring Remaining Moisture Content in a Residential Clothes Washer,'' published in May 2000. See 66 FR 3314, 3317.

the test procedures for these products should include consistent water supply pressure specifications. DOE noted, however, that the test data suggested a water supply pressure of 20 psig under flow conditions for the most consistent water use among different cycles for a given clothes washer. DOE's analysis indicated that 20 psig may represent typical static pressure under flow conditions that would result from 35 psig at non-flow conditions, and that these conditions may be more representative of water supply conditions that would be found in typical residential settings.

In the September 2010 NOPR, DOE did not propose to specify water supply pressure more closely. DOE asked for stakeholders to provide any relevant information about the conditions under which clothes washers are currently tested, and invited comment on the appropriate specification of the water supply pressure. DOE received the following information and comments from interested parties regarding the water supply pressure requirements in the existing clothes washer test procedure.

ALS and AHAM support retaining the current specifications for static water supply pressure. ALS and AHAM suggested that DOE specify a ''dynamic water pressure'' of 35 psi ± 2.5 psi. AHAM stated that dynamic water pressure affects the test results, and ALS stated that dynamic water pressure is the most important water supply pressure. (ALS, No. 10 at p. 5; AHAM, No. 14 at p. 16).

Springboard stated that clothes washers with higher flow rates could require extra-high water pressure to regulate the pressure to 35 psi during water fill. (Springboard, No. 11 at p. 3).

NEEA stated that water pressure should be specified under flow conditions (not static pressure), and the value should be the same as for the dishwasher test procedure (35 psi). NEEA presented data from research conducted by the American Water Works Association (AWWA) that indicates a range of average water system static pressures from 45 psi to 80 psi, with occasional outliers. According to NEEA, discussions with rural water systems contractors suggest normal system pressure setpoints of 25 and 55 psi for pump on and pump off, respectively. NEEA further stated that studies of municipal water system pressures tend to find a static pressure range of 45 to 100 psi, depending on where in the system one measures. NEEA stated that because municipal water system pressures are designed to maintain pressure under high flow rates at fire hydrants and standpipes, communities are unlikely to have flowing pressure conditions less than 35 psi. Therefore, NEEA believes that 35 psi is a reasonable estimate for most residential households. (NEEA, No. 12 at pp. 14–15; NEEA, Public Meeting Transcript, No. 20 at pp. 203–204) Whirlpool commented that it supports 35 psi ± 2.5 psi under ''dynamic flow conditions.'' (Whirlpool, No. 13 at p. 14).

The Joint Commenters commented that a static pressure under non-flow conditions of 35 psi is significantly lower than actual system operating pressures. They stated that a test rig calibrated to maintain a static pressure of 35 psi will yield a flowing water pressure that is significantly less than 35 psi. The Joint Commenters also noted that the California-American Water Company reports one small sub-district with an operating pressure of 40 psi, while all other service areas have average operating pressures of 60 to 80 psi. They also observed that the Philadelphia Water Department reported an average operating pressure of 55 psi during fiscal year 2008. The Joint Commenters believe that a water supply test pressure of 35 psi under flow conditions would better represent typical water supply pressures found in homes, and would align the clothes washer test procedure with the dishwasher test procedure. The Joint Commenters further commented that DOE's proposed definition of water pressure contains both ''static'' and ''flowing'' in the same sentence. NRDC suggested that the word ''static'' be removed from the definition to remove ambiguity and a potentially significant source of unintended variation in test results. (Joint Commenters, No. 16 at pp. 8–9; Joint Commenters, No. 23 at pp. 5–6).

The California Utilities recommend that DOE clarify whether the water supply pressure specified in the proposed test procedure should be maintained at flow or non-flow conditions. The California Utilities also recommend that DOE specify that the water supply pressure be maintained at 35 psig when the water is flowing, which will maintain consistency with the dishwasher test procedure. The California Utilities stated that this would be an appropriate water pressure for much of the residential sector across the country. (California Utilities, No. 18 at p. 5).

DOE notes that nearly all interested parties recommended specifying a water pressure of 35 psi during water flow conditions. DOE further notes that the clothes washer water consumption will be most heavily affected by the water pressure during flow conditions rather than the water pressure during non-flow conditions. Therefore, DOE agrees that the water pressure specification should be specified during flow conditions.

DOE recognizes that the term ''pressure'' must be further qualified to remove ambiguity regarding the water supply conditions. In referring to the pressure in fluid systems, ''static'' does not imply that the fluid is stationary; rather, the term ''static'' represents the pressure exerted in all directions by the fluid. Static pressure is the type of pressure most commonly measured by typical instrumentation. When the water is stationary, the static pressure is highest and represents the total pressure in the system. As the water begins flowing, some of the static pressure is converted to ''dynamic pressure,'' which is the kinetic energy of the fluid per unit volume. Thus, during flow conditions, the static pressure decreases at the same time that dynamic pressure increases.

Because the intent of the test procedure is to specify the typically measured pressure of the water during flow conditions, DOE believes that the definition it proposed in the September 2010 NOPR correctly specifies measuring the static water pressure while the water is flowing. Removing the term ''static water pressure'' could create ambiguity about which type of water pressure should be measured (*i.e.,* static pressure, dynamic pressure, or total pressure). Similarly, replacing the term ''static water pressure'' with ''dynamic water pressure'' could result in an incorrect measurement being performed, since ''dynamic water pressure'' has a different, specific meaning in the context of fluid flow and is not equivalent to the pressure typically measured during flow conditions. For these reasons, today's final rule incorporates the change to the water pressure specification in the new appendix J2 test procedure as proposed in the September 2010 NOPR.

Water Inlet and Drain Hoses

In response to the September 2010 NOPR, Whirlpool commented that appendix J2 should adopt three additional test setup requirements that can affect water and energy consumption. First, Whirlpool suggested that the length of the inlet water hoses be defined as the standard hose length of 48 inches, as this would avoid an inadvertent impact on hot water usage. Second, Whirlpool suggested that the length of the drain hose should be defined as not to exceed 72 inches. Third, Whirlpool suggested

that the drain pipe height should be between 38 and 54 inches. Whirlpool stated that adoption of these specifications will significantly reduce variation between laboratories. (Whirlpool, No. 13 at p. 14).

DOE notes that Section 2.1 of the test procedure requires the clothes washer to be installed in accordance with manufacturer's instructions, which would include installation of the water inlet and drain hoses supplied with each new clothes washer. Therefore, DOE believes the test procedure should not separately specify the length of the inlet and drain hoses. Regarding the height of the drain pipe, DOE has no data with which to evaluate Whirlpool's suggested height requirement. Therefore, DOE is unable to determine the impact on test results due to the height of the drain pipe. For these reasons, today's final rule does not adopt Whirlpool's suggested requirements regarding water inlet and drain hoses.

8. Clarifications and Corrections

Correction of Cold Rinse Definition

After the publication of the September 2010 NOPR, DOE became aware of an error in the definition of ''cold rinse'' in the test procedure at appendix J1. Specifically, cold rinse is defined in section 1.22 of appendix J1 as ''the coldest rinse temperature available on the machine (and should be the same rinse temperature selection tested in 3.7 of this appendix).'' However, section 3.7 of appendix J1 contains provisions for testing warm rinse, which instruct that such tests be conducted with the hottest rinse temperature available. Thus, section 3.7 is inapplicable to the definition of cold rinse in section 1.22. In the August 2011 SNOPR, DOE proposed to remove reference to section 3.7 in the definition of cold rinse in both section 1.22 of appendix J1 and proposed section 1.7 of appendix J2.

Whirlpool and AHAM agree with DOE's proposal to correct the definition of cold rinse. (Whirlpool, No. 27 at p. 4; AHAM, No. 24 at p. 3) DOE received no comments on these revisions. Therefore, for the reasons stated above and in the August 2011 SNOPR, DOE incorporates these changes into the amendments to the appendix J1 test procedure and the new appendix J2 test procedure in today's final rule as proposed in the August 2011 SNOPR.

Clarification of Wash Time Setting for Electromechanical Dials

Section 2.10 of the current test procedure specifies the wash time setting to be used in the energy test cycle. If only one wash time is prescribed in the energy test cycle, that wash setting is to be used; otherwise, the wash time setting is required to be the higher of either the minimum wash time or 70 percent of the maximum wash time available in the energy test cycle. As described in the August 2011 SNOPR, DOE has become aware that, for certain clothes washers equipped with an electromechanical dial to control wash time, the dial may yield different results for the same setting depending on the direction in which the dial was turned to reach that setting. DOE's internal testing indicates that that consistency in setting the wash time in such cases may be achieved by resetting the dial to the minimum wash time and then turning it in the direction of increasing wash time to reach the desired setting. If the desired setting is passed, the dial should not be turned in the direction of decreasing wash time to reach the setting. Instead, the dial should be returned to the minimum wash time and then turned in the direction of increasing wash time until the desired setting is reached. In the August 2011 SNOPR, DOE proposed to add these clarifications to the provisions for setting the wash time in both appendix J1 and appendix J2.

To provide further consistency, DOE also proposed the additional clarification that the conditions stated in the case of more than one wash time setting—that the wash time setting shall be the higher of either the minimum, or 70 percent of the maximum wash time available in the energy test cycle—shall apply regardless of the labeling of suggested dial locations.

Springboard stated that use and care manuals sometimes do not prescribe a wash time for each cycle. Springboard also commented that currently the appendix J1 test procedure does not specify whether the 70 percent wash time provision applies to machines with electromechanical or electronic controls. Springboard questioned whether a default setting on the machine should be used, or whether the cycle and time labeled in bold on the control panel should be the prescribed setting. Springboard further noted that on a mechanical dial, it is not always possible to achieve the same wash time setting. (Springboard, No. 11 at p. 3).

AHAM does not oppose DOE's proposed clarifications to appendices J1 and J2 regarding the wash time setting. (AHAM, No. 24 at p. 4) ALS supports DOE's proposal to achieve consistency in obtaining the wash time setting on machines with electromechanical dials. ALS stated that the proposed changes would reduce variability in test results. Furthermore, ALS supports the proposal to add the phrase ''regardless of the labeling of suggested dial locations'' to clarify the existing requirement that ''the wash time setting shall be the higher of either the minimum or 70 percent of the maximum wash time available in the energy test cycle.'' (ALS, No. 22 at p. 3).

DOE has observed that clothes washers with electronic controls have a default wash time setting for each cycle; this default time would be considered the ''prescribed'' wash time setting. Therefore, the provision stating ''the wash time setting shall be the higher of either the minimum or 70 percent of the maximum wash time available in the energy test cycle'' applies only to electromechanical controls, where the user is required to manually set the wash time by turning the wash setting dial. DOE's proposal would clarify that this wash time requirement would apply ''regardless of the labeling of suggested dial locations.'' This would include any labels in bold or other markings suggesting particular locations on the dial.

DOE received no comments objecting to its proposed revisions regarding the wash time setting provisions of the test procedure. Therefore, for the reasons discussed above, DOE incorporates these changes into the amendments to the appendix J1 test procedure and the new J2 test procedure in today's final rule.

Clarification of Cold Wash Definition

As described in the August 2011 SNOPR, DOE has observed multiple clothes washer models that offer a ''tap cold'' wash temperature setting in addition to a ''cold'' wash temperature setting. DOE proposed to clarify how to classify these temperature selections in appendix J1 and appendix J2.

Section 3.6 of appendix J1 defines the cold wash selection as ''the coldest wash temperature selection available.'' Additionally, section 1.18 of appendix J1 defines ''warm wash'' as ''all wash temperature selections below the hottest hot, less than 135 °F, and above the coldest cold temperature selection.'' In some cases with these models, DOE has observed that the ''cold'' setting mixes in hot water to raise the temperature above the cold water supply temperature, as defined in section 2.3 of appendix J1. In such cases, DOE proposes that the manufacturer specified ''cold'' setting should be considered a warm wash, as defined in section 1.18 of appendix J1 and section 1.34 of appendix J2; and that the ''tap cold'' setting should be considered the cold wash, as defined in section 3.6 of

both appendix J1 and appendix J2. In cases where the ''cold'' setting does not add any hot water for any of the test loads required for the energy test cycle, the ''cold'' setting should be considered the cold wash; and the ''tap cold'' setting would not be required for testing.

AHAM, Whirlpool, and NEEA support the proposed clarification regarding cold wash temperature selection (AHAM, No. 24 at p. 4; Whirlpool, No. 27 at p. 3; NEEA, No. 26 at p. 7). DOE received no comments objecting to its proposed revisions regarding the clarification of the cold wash temperature. Therefore, for the reasons discussed above, DOE incorporates these changes into the amendments to the appendix J1 test procedure and the new J2 test procedure in today's final rule.

Removal of Obsolete Note in Water Factor Calculation Section

In the current test procedure at appendix J1, section 4.2 provides instructions for calculating the water consumption of clothes washers. Currently, this section includes the following note:

(The calculations in this Section need not be performed to determine compliance with the energy conservation standards for clothes washers).

EPCA established a water factor standard for top-loading and front-loading standard-size residential clothes washers, so this note is now obsolete. The calculations in section 4.2 must be performed to determine compliance with energy conservation standards for these product classes. Today's final rule removes this note in both appendix J1 and appendix J2.

Correction of Typographical Error in Hot Water Consumption Calculation

Section 4.1.4 of the existing clothes washer test procedure calculates the total per-cycle hot water energy consumption using gas-heated or oil-heated water. The equation listed in this section contains a clerical error in the symbol for total weighted per-cycle hot water energy consumption. In the September 2010 NOPR, DOE proposed amending the equation in this section to replace the incorrect symbol, H_T, with the correct symbol, HE_T. DOE would apply this amendment to both existing appendix J1 and new appendix J2.

AHAM supports DOE's proposed correction to the symbol for total weighted per-cycle hot water energy consumption. (AHAM, No. 14 at p. 16) DOE received no comments objecting to this revision. Therefore, for the reasons stated above, DOE incorporates these changes into the amendments to the appendix J1 test procedure and the new J2 test procedure.

Removal of Energy Factor Calculation

Section 4.5 of the current clothes washer test procedure provides for the calculation of Energy Factor (EF). EF was the energy efficiency metric used to establish energy conservation standards for clothes washers manufactured before January 1, 2004. (10 CFR 430.32(g)) This metric is no longer used to determine compliance with energy conservation standards, or in any other related metrics. Therefore, DOE proposed in the September 2010 NOPR to remove the obsolete calculation of EF from the clothes washer test procedure.

AHAM supports DOE's proposal to remove the obsolete calculation of EF from the clothes washer test procedure. (AHAM, No. 14 at p. 17) DOE received no comments objecting to this revision. Therefore, for the reasons stated above, DOE incorporates this change into the amendments to the appendix J1 test procedure and the new appendix J2 test procedure.

Clarification of Waiver Field Test Equation

In response to the August 2011 SNOPR, AHAM commented that section 6.2 of the test procedure regarding field testing needs clarification. AHAM stated further that the equation in section 6.2 is confusing. (AHAM, No. 24 at p. 6)

Section 6.2 in the appendix J1 test procedure provides describes one possible method for determining the energy consumption of a clothes washer with a nonconventional wash system. Generally, the method described in this section involves field testing both the nonconventional clothes washer as well as a conventional clothes washer; developing a scaling factor by comparing the conventional clothes washer's rated energy consumption and field test energy consumption; and applying this scaling factor to the nonconventional clothes washer to determine an appropriate rating based on its field test results.

The equation provided in Section 6.2 was created when EF was the only metric used to determine compliance with energy conservation standards for clothes washers. Therefore, it does not include provisions for measuring the energy required for moisture removal (*i.e.,* drying energy), which is a component of MEF, or for measuring the water consumption factor. Therefore, this equation is no longer applicable and should be removed. Today's final rule amends Section 6.2 in both appendix J1 and the newly created appendix J2 by removing the specific example, including the equation, and modifying the general provisions so that the section is applicable to MEF and WF. The amendment to appendix J2 contains an additional instruction to measure standby and off mode power according to the provisions in the relevant sections of the test procedure.

Clarification of Water Factor Terminology

DOE notes the use of inconsistent terminology to describe the water consumption factor (or water factor) among the clothes washer test procedure, clothes washer energy conservation standards, annual operating cost calculations, and certification, compliance, and enforcement requirements for clothes washers.

The clothes washer energy conservation standards use the terminology ''water factor,'' and DOE has observed that the term ''water factor'' has been used more often than ''water consumption factor'' during previous rulemakings and within public comments submitted by interested parties. DOE has also observed that ''water factor'' is the term most commonly used within the clothes washer industry. Therefore, today's final rule replaces the term ''water consumption factor'' with ''water factor'' in the appendix J1 test procedure, the newly created appendix J2 test procedure, and the annual operating cost calculations for clothes washers in 10 CFR 430.23(j). In addition, today's final rule replaces the abbreviation ''WCF'' with ''WF'' in the appendix J1 test procedure and the newly created appendix J2 test procedure.

9. Test Procedure Performance Specifications

In response to the August 2009 standards framework document, DOE received multiple comments in support of adding performance measures to the clothes washer test procedure, which it addressed in the September 2010 NOPR. DOE carefully considered these comments but did not propose to incorporate measures of wash performance into the clothes washer test procedure. DOE noted that EPCA states ''[a]ny test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use * * * or estimated annual operating cost of a covered product during a representative average use cycle or period of use * * *

and shall not be unduly burdensome to conduct.'' 42 U.S.C. 6293(b)(3). DOE stated, however, that it would consider wash performance and related impacts to consumer utility in developing any future energy conservation standards for residential clothes washers.

In response to the September 2010 NOPR, DOE received multiple comments regarding the inclusion of performance measures in the clothes washer test procedure. AHAM and NEEA support DOE's proposal to not incorporate wash performance into the test procedure. AHAM stated that DOE should consider it later should data on the feasibility of incorporating a measure of wash performance become available. NEEA commented that there is no justification for including such metrics in a test procedure, which is required by EPCA to measure energy and water use and to provide a means to estimate annual operating cost. (AHAM, No. 14 at p. 17; NEEA, No. 12 at p. 15) ALS stated that generally, the residential clothes washer test procedure is adequate for measuring energy consumption and water consumption of both residential and commercial clothes washers, as long as the minimum efficiency standard for commercial clothes washers takes into account the consumer utility needed for the commercial washer application. (ALS, No. 10 at p. 6).

BSH commented that wash performance should be included, and that the clothes washer should be rated based on the quantity of laundry can successfully be washed rather than the physical size of the clothes container. (BSH, No. 17 at p. 4; BSH, Public Meeting Transcript, No. 20 at p. 211) BSH stated that manufacturer-rated load weight accompanied by performance assessments are the only way to fairly compare top-load and front-load clothes washer capabilities. (BSH, No. 17 at p. 4).

China commented that the testing conditions proposed by DOE for various temperature settings are different than the test conditions required by IEC Standard 60456, ''Clothes washing machines for household use–Methods for measuring the performance,'' Edition 5.0. China recommended that DOE apply the same test conditions as IEC Standard 60456, or specify testing temperatures by referencing IEC Standard 60456 test conditions, to avoid creating unnecessary barriers to trade. China stated that IEC Standard 60456 test conditions establish a clear value for the supply water temperatures, compared to the range of water temperatures provided in DOE's proposed rule, and that this could lead to confusion. (China, No. 19 at p.4).

In response, DOE reiterates that it currently considers any lessening of the utility or the performance of a covered product likely to result from the imposition of any energy conservation standard. 42 U.S.C. 6295(o)(2)(B)(i)(IV) Furthermore, DOE may not prescribe a standard that is likely to result in the unavailability in the United States of performance characteristics, including reliability. 42 U.S.C. 6295(o)(4) As stated above, EPCA requires that DOE test procedures must be reasonably designed to produce test results that measure energy efficiency, energy use, water use in specified instances, or estimated annual operating cost of a covered product during a representative use cycle or period of use. 42 U.S.C. 6293(b)(3).

D. Annual Operating Cost Calculation

DOE did not propose in the September 2010 NOPR to amend the estimated annual operating cost calculation in 10 CFR 430.23 to include the cost of energy consumed in the non-active washing modes. DOE noted that the cost of energy consumed in self-clean, standby, off, delay start, and cycle finished modes is small relative to the total annual energy cost for clothes washers and, therefore, would make little difference in the estimated annual operating cost calculation. In addition, the Federal Trade Commission's (FTC's) EnergyGuide Label for clothes washers includes as its primary indicator of product energy efficiency the estimated annual operating cost, compared to a range of annual operating costs of similar products. Appendix F1 to 16 CFR part 305. An estimated annual operating cost incorporating self-clean, standby, off, delay start, and cycle finished mode energy use would no longer be directly comparable to the minimum and maximum energy costs currently prescribed for the EnergyGuide Label.

Upon further consideration, DOE proposed in the August 2011 SNOPR to amend the annual energy cost calculations to include the cost of energy consumed in non-active washing modes. As discussed in the August 2011 SNOPR, EPCA requires that 180 days after the amended test procedure is prescribed, all representations related to the energy use, efficiency, or cost of energy consumed for residential clothes washers must reflect the results of testing according to the amended test procedure. 42 U.S.C. 6293(c)(2) Also, the definition of ''estimated annual operating cost'' is the aggregate retail cost of the energy likely to be consumed annually in representative use of a consumer product, determined in accordance with section 6293 of this title. 42 U.S.C. 6291(7) The test procedure established in today's final rule includes provisions for measuring standby and off mode energy use. Additionally, EPCA requires that any revisions to the labels for residential clothes washers include disclosure of the estimated annual operation cost (determined in accordance with DOE's test procedures prescribed under section 6293 of EPCA), unless the Secretary determines that disclosure of annual operating cost is not technologically feasible, or if the FTC determines that such disclosure is not likely to assist consumers in making purchasing decisions or is not economically feasible. 42 U.S.C. 6294(c)(1).

DOE received additional comments from interested parties in response to its proposal in the August 2011 SNOPR. AHAM opposes revision of estimated annual operating cost to incorporate standby, off and self-clean modes. AHAM stated that the cost of energy associated with each individual mode makes little difference in the annual operating cost. AHAM claims the increased test burden in measuring these modes and incorporating them in the annual energy cost is not justifiable. AHAM further stated that if, however, DOE revises the estimated annual operating cost calculation, DOE and FTC should provide adequate time for collection of data on operating costs before the new integrated approach goes into effect. (AHAM, No. 24 at p. 3) NEEA agrees with DOE's proposal to include non-active washing mode energy use in the calculation of energy cost. (NEEA, No. 26 at p. 7).

DOE notes that the revised test procedure at appendix J2 implements the ''alternate approach'' for measuring standby and off mode energy use, which minimizes the additional test burden required for performing these measurements. In addition, the revised test procedure does not require measurement of self-clean mode.

For the reasons stated in the August 2011 SNOPR, DOE amends the annual energy cost calculations in 10 CFR part 430.23 for residential clothes washers to include the cost of energy consumed in standby and off modes. Therefore, today's final rule amends the clothes washer test procedure to revise the estimated annual operating cost calculation to integrate standby and off mode energy use, as proposed in the August 2011 SNOPR.

E. Revisions to Appendix J1

The following sections describe amendments to the current appendix J1 in today's final rule. These changes are discussed in more detail previously but are set forth here to clearly describe those changes that are applicable to appendix J1, use of which is currently required to demonstrate compliance with existing energy conservation standards. In any rulemaking to amend a test procedure, DOE must determine to what extent, if any, the proposed test procedure would alter the measured energy efficiency of any covered product as determined under the existing test procedure. 42 U.S.C. 6293(e)(1) If DOE determines that the amended test procedure would alter the measured efficiency of a covered product, DOE must amend the applicable energy conservation standard accordingly. 42 U.S.C. 6293(e)(2) DOE has determined that none of the following amendments to appendix J1 would alter the measured efficiency of residential clothes washers. The amendments to appendix J1 are effective 30 days after publication of this final rule in the **Federal Register**.

1. Revision of Introductory Text

Today's final rule revises the introductory text of appendix J1 after the appendix heading to note that manufacturers may continue to use appendix J1 until the compliance date of any amended standards that address standby and off mode energy consumption for residential clothes washers. After this date, all residential clothes washers shall be tested using the provisions of appendix J2. This introductory note is also included at the beginning of appendix J2.

2. Correction of Typographical Errors in Materials Incorporated by Reference

The current DOE test procedure at appendix J1 contains an incorrect mailing address in section 2.6.4.5.3(b) for the American Association of Textile Chemists and Colorists. The correct address is P.O. Box 12215. Today's final rule corrects this typographical error. Today's final rule also updates the contact telephone number to (919) 549–3526, which is listed on the cover page of the current versions of the AATCC standards.

3. Correction of Cold Rinse Definition

As discussed previously in section III.C.8.a, today's final rule corrects the definition of cold rinse in section 1.22 of appendix J1 by removing the incorrect reference to section 3.7.

4. Removal of Redundant Sections

As discussed previously in section III.C.6.k, this final rule removes the redundant sections 2.6.1.1–2.6.1.2.4 in appendix J1, which were made obsolete by the 2001 Final Rule. Today's final rule also maintains the thread count specification from deleted section 2.6.1.1(A), of 65 x 57 per inch (warp x fill) by moving it to section 2.6.4.3.

5. Detergent Specification and Dosage

As discussed previously in section III.C.6.c, this final rule specifies the use of AHAM standard test detergent Formula 3 in test cloth preconditioning, at a dosing of 27.0g + 4.0g/lb.

6. Wash Time Setting for Electromechanical Dials

As discussed previously in section III.C.8.b, this final rule adds clarification to the wash time setting provisions in section 2.10 of appendix J1 to help ensure consistency when setting the wash time on clothes washers with electromechanical dials.

7. Clarification of Cold Wash Definition

As discussed previously in section III.C.8.c, this final rule adds clarification to the cold wash definition in section 3.6 of appendix J1 for clothes washers that offer a ''tap cold'' wash temperature setting in addition to a ''cold'' wash temperature setting.

8. Removal of Obsolete Note in Water Factor Calculation Section

As discussed previously in section III.C.8.d, this final rule removes an obsolete note in section 4.2 of appendix J1, which states that the water factor calculations need not be performed to determine compliance with the energy conservation standards for clothes washers.

9. Clarification of Water Factor Terminology

As discussed previously in section III.C.8.h, this final rule replaces the term ''water consumption factor'' with ''water factor'' in sections 1.19 and 4.2.3 of appendix J1.

10. Correction of Typographical Error in Hot Water Consumption Calculation

As discussed previously in section III.C.8.e, this final rule amends the equation in section 4.1.4 of appendix J1 to replace the incorrect symbol, H_T, with the correct symbol, HE_T.

11. Extension of Test Load Size Table

As discussed previously in section III.C.3.b, this final rule extends Table 5.1 in appendix J1 to accommodate clothes washers with capacities up to 6.0 cubic feet.

12. Clarification of Waiver Field Test Equation

As discussed previously in section III.C.8.g, this final rule modifies the provisions in section 6.2 in appendix J1 by removing the specific example, including the equation, and modifying the general provisions so that the section is applicable to MEF and WF.

13. Corrections to Provisions for Calculating the RMC Correction Curve

As discussed previously in section III.C.6.j, this final rule corrects typographical and transcription errors in the formula given in section 2.6.6.1 of appendix J1. This final rule also amends the description of the analysis of variance test to be performed in section 2.6.6.2 to make the analysis details more explicit and technically accurate.

F. Removal of Obsolete Test Procedure at Appendix J

In the September 2010 NOPR, DOE proposed to delete appendix J to subpart B of 10 CFR part 430 along with all references to appendix J in 10 CFR 430.23. Appendix J applies only to clothes washers manufactured before January 1, 2004 and is therefore obsolete. Appendix J1 to subpart B of 10 CFR part 430 provides an applicable test procedure for all clothes washers currently available on the market. DOE proposed to maintain the current naming of appendix J1, rather than renaming it as appendix J, and to establish new appendix J2 to simplify the changes required.

NEEA supports DOE's proposal to eliminate appendix J and to add appendix J2. (NEEA, No. 12 at p. 16) Therefore, for the reasons discussed above, DOE eliminates appendix J along with all references to appendix J.

G. Compliance With Other EPCA Requirements

1. Test Burden

As noted previously, under 42 U.S.C. 6293(b)(3), EPCA requires that ''[a]ny test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use * * * or estimated annual operating cost of a covered product during a representative average use cycle or period of use * * * and shall not be unduly burdensome to conduct.'' DOE tentatively concluded in the September 2010 NOPR that amending the relevant DOE test procedures to incorporate clauses regarding test conditions and

methods found in IEC Standard 62301, along with the proposed modifications to the active washing mode test procedure, would satisfy this requirement.

DOE received numerous comments regarding test burden in response to the September 2010 NOPR. DOE addressed some of these comments specifically related to delay start mode and cycle finished mode test burden in the August 2011 SNOPR. DOE responds to the remaining comments here.

Whirlpool stated that the proposed measurement of energy and water consumption in delay start, cycle finished, self-clean, off modes, additional rinses, etc. would increase manufacturer test burden by as much as 25 percent. Whirlpool commented that it does not have sufficient ''slack'' capacity to manage such an increase in test burden because its laboratories are currently operating at full capacity on two shifts. Whirlpool stated that the cost of utilizing third-party laboratories for this added testing would be substantial and could exceed $500,000 annually. Whirlpool added that the proposed revision of the energy test cycle definition could double or quadruple the length of the test process for any clothes washer for which Part (B) of the proposed energy test cycle definition applies. Whirlpool believes that this additional test burden would not be justifiable. (Whirlpool, No. 13 at pp. 1, 13).

AHAM commented that additional measurements required by the proposed rule would be burdensome and would result in only a *de minimus* amount of additional measured energy (as little as zero additional energy in the case of cycle finished mode). AHAM stated that DOE should not substantially increase the testing burden on manufacturers when the result would not produce significant conservation of energy and thus little or no benefit to the public interest. (AHAM, No. 14 at p. 2) AHAM stated that measuring *de minimus* amount of standby power energy would require large amounts of testing time. AHAM believes that DOE's estimate of an 11 percent increase in the testing duration for clothes washers offering inactive, off, delay start, and cycle finished modes would be significant, and AHAM predicts that the increase in test duration could actually be as much as 25 percent. AHAM believes that separately measuring delay start and cycle finished mode represents a significant increase in the testing burden, without any corresponding public benefit. (AHAM, No. 14 at pp. 4, 15) Furthermore, AHAM stated that adding steam cycles to the test procedure would add substantially to the test burden. (AHAM, No. 14 at p. 10).

BSH commented that its calculations indicate appendix J1 requires three days of dedicated testing for each appliance. BSH believes this is already a significant burden for appliance testing, particularly as compared to clothes dryers and other appliances. BSH estimated that the worst-case proposal in the September 2010 NOPR would represent a 47 percent increase in testing time for each clothes washer, for a total testing time of one full work week. BSH stated that to perform this additional testing, laboratory facilities and available labor would need to be increased by around 50 percent, or external resources sought, which would delay product innovation. BSH also estimated that should self-cleaning and steam cycles be excluded from testing, and should delay start and cycle finished modes be included in off and inactive modes rather than separately measured, the increase in test burden would be approximately 15 percent. BSH believes that this level of testing increase is manageable. Finally, BSH estimated that should the definition of energy test cycle be implemented as proposed in the September 2010 NOPR, test burden could increase by 100 percent or more depending on how the phrase ''largely comparable'' is interpreted and defined. (BSH, No. 17 pp. 5–6).

NEEA believes that any increased test burden resulting from DOE's proposal will be minor in comparison to the significant amount of testing that manufacturers conduct as part of product development, and in testing their competitors' products. NEEA stated that much of the added test burden, such as burden associated with testing inactive mode, non-active wash mode power consumption, and steam cycles will be associated with only a subset of the models produced. (NEEA, No. 12 at p. 15).

The California Utilities commented that the test procedure proposed by DOE in the September 2010 NOPR represents an improvement over the current J1 test procedure, and does not appear to significantly add to the testing burden. The California Utilities stated that testing of delay start, cycle finished, and self-clean modes should apply only to those models that include those features (or in the case of self-clean mode, those models with a manufacturer recommendation for periodic self-clean cycles), and therefore would alter the testing burden only for those products. The California Utilities also stated that because measurement of hot water is already incorporated in the test procedure for the MEF calculation, inclusion of hot water in the proposed IWF calculation will not introduce any significant test burden. (California Utilities, No. 18 at pp. 1, 2, 5).

In the August 2011 SNOPR, DOE proposed supplemental amendments to the clothes washer test procedure, which incorporated the most current version of IEC Standard 62301 (Second Edition) instead of the previous version. DOE also proposed certain amendments to the active mode provisions of the test procedure. As explained in the August 2011 SNOPR, DOE tentatively concluded that the new provisions in IEC Standard 62301 (Second Edition) would improve test results without undue test burden. DOE also stated its belief that the potential for increased test burden for certain power measurements is offset by more reasonable requirements for testing equipment, while maintaining acceptable measurement accuracy. In addition, the proposed amendments to the active mode provisions consist of clarifications and would not require any additional investment, equipment purchases, or test time beyond those described in the September 2010 NOPR. Therefore, DOE tentatively concluded that the proposed active mode amendments would not impose significant burden on manufacturers.

The California Utilities support the harmonization of the test procedure with IEC Standard 62301 (Second Edition). The California Utilities stated that the potential test burden on manufacturers is outweighed by the improvement in accuracy and representativeness of the resulting power measurement. The California Utilities stated further that the increased testing time and the use of analytical software associated with using the Second Edition is required only for unstable and non-cyclical power measurements, and because the expected number of instances of unstable and non-cyclical power should be small, the added test burden should likewise remain minimal. (California Utilities, No. 25 at p. 1).

NEEA believes that the extra time required for measuring unstable power modes is justified for obtaining an accurate measurement. NEEA believes that for clothes washers requiring the most extreme increase in test burden, manufacturers will quickly learn the behavior of their products' standby and off mode behavior and choose the appropriate measurement technique accordingly. (NEEA, No. 26 at p. 2) NEEA also suggested that setting time limits on the duration of delay start and

cycle finished mode can limit the test burden associated with measuring power in these modes. (NEEA, No. 26 at pp. 2–3) NEEA disagrees with Whirlpool's claim that there is virtually no consumer benefit in measuring power consumption in low-power modes. (NEEA, No. 26 at p. 3).

DOE notes that interested parties generally support harmonizing the test procedure with the Second Edition of IEC Standard 62301, and that the test procedure improves accuracy and consistency of test results and is not unduly burdensome to conduct. As described previously, DOE adopts the ''alternate approach'' in which all low-power mode hours are allocated to the inactive and off modes, and the low-power mode power is only measured in the inactive and off modes, depending on which of these modes is present. Under the alternate approach, additional measurements of delay start mode and cycle finished mode are not required. Today's final rule also does not require the separate measurement of self-clean mode. In addition, the large majority of amendments to the active mode provisions of the test procedure consist of clarifications to test conduct and revised calculations, and would not require any additional investment, equipment purchases, or test time beyond those described in the September 2010 NOPR. DOE believes that any additional test burden resulting from the revised definition of the energy test cycle will be minimal because manufacturers already possess in-depth knowledge about the energy characteristics of each wash cycle offered on their clothes washers. Other test laboratories would not be required to conduct multiple tests to determine which cycle settings should be included under Part (B) of the energy test cycle, which could actually reduce test burden. For these reasons, DOE concludes that today's amendments to the provisions for standby mode, off mode, and active mode provisions of the clothes washer test procedure will not impose significant additional test burden on manufacturers.

2. Integration of Standby Mode and Off Mode Energy Consumption Into the Energy Efficiency Metrics

As discussed previously, EPCA requires that standby mode and off mode energy consumption be integrated into the overall energy efficiency, energy consumption, or other energy descriptor for each covered product unless the current test procedures already fully account for the standby mode and off mode energy consumption or if an integrated test procedure is technically infeasible. 42 U.S.C. 6295(gg)(2)(A) As described in section III.B.8, DOE adds provisions in this final rule for calculating the integrated modified energy factor, which integrates the combined low-power mode energy consumption into the overall energy efficiency metric for clothes washers.

EPCA also provides that test procedure amendments adopted to comply with the new EPCA requirements for standby and off mode energy consumption will not be used to determine compliance with previously established standards. 42 U.S.C. 6295(gg)(2)(C) Because DOE is incorporating these changes in a new appendix J2 to 10 CFR part 430 subpart B that manufacturers would not be required to use until the compliance date of amended energy conservation standards for residential clothes washers, the test procedure amendments pertaining to standby mode and off mode energy consumption that DOE adopts in this rulemaking do not apply to, and have no effect on, existing standards.

3. Impacts on Commercial Clothes Washers

The test procedure for commercial clothes washers is required to be the same test procedure established for residential clothes washers. 42 U.S.C. 6314(a)(8) Thus, the test procedure set forth in appendix J1 of subpart B of 10 CFR part 430 is also currently used to test commercial clothes washers. 10 CFR 431.154

DOE noted in the September 2010 NOPR that the impacts on testing commercial clothes washers would be limited to the proposed amendments associated with active washing mode because commercial clothes washer standards are based on MEF and WF. These include the proposed changes to the test load size specification, TUFs, DUF, test cloth specification, capacity measurement, detergent specification, and water supply pressure specification, which would affect the measured energy and water efficiencies of a commercial clothes washer. DOE stated that the most significant impacts would be associated with the proposed amendments for capacity measurement and usage factors, but did not have information to evaluate any impacts for commercial clothes washers.

DOE received several comments on the potential impacts of an amended clothes washer test procedure on commercial clothes washers and provided responses to most of these comments in the August 2011 SNOPR. NEEA provided one additional comment on the September 2010 NOPR. NEEA stated that most of the provisions of the new appendix J2 test procedure will be relevant to the testing and rating of commercial clothes washers. NEEA notes, however, that DOE's current projected schedule for a new commercial clothes washer rulemaking estimates a final rule in 2015, which would result in an effective date of new standards for these products in 2018. NEEA suggests that DOE explore the possibility of expediting the projected rulemaking schedule for commercial clothes washers to more closely align the metrics and marketplace performance perceptions of the residential and commercial products. (NEEA, No. 12 at p. 15).

DOE also received the following comments from the August 2011 SNOPR. AHAM and ALS agree with DOE's clarification that the impact on commercial clothes washers would be limited to the proposed amendments associated with active washing mode, since commercial clothes washer standards are based on MEF and WF, which do not include standby and off mode. (AHAM, No. 24 at p. 6; ALS, No. 22 at p. 4).

For the reasons discussed above and in the August 2011 SNOPR, DOE concludes that the addition of procedures to measure the energy use in standby and off modes would be inapplicable to and would not affect the standards for commercial clothes washers pursuant to 42 U.S.C. 6293(e). For the active mode provisions of the revised test procedure that could affect the measured energy and water efficiencies of a commercial clothes washer, DOE notes that 42 U.S.C. 6293(e)(3) provides the following: Models of covered products in use before the date on which an amended energy conservation standard (developed using the amended test procedure pursuant to 42 U.S.C. 6293(e)(2)) becomes effective that comply with the energy conservation standard applicable to such covered products on the day before such date are deemed to comply with the amended standard. The same is true of revisions of such models that come into use after such date and have the same energy efficiency, energy use or water use characteristics.

4. Certification, Compliance, and Enforcement Requirements

Sections 6299–6305 and 6316 of EPCA authorize DOE to enforce compliance with the energy and water conservation standards established for certain consumer products and commercial equipment. 42 U.S.C. 6299–6305 (consumer products), 6316

(commercial equipment) On March 7, 2011, the Department revised, consolidated, and streamlined its existing certification, compliance, and enforcement regulations for certain consumer products and commercial and industrial equipment covered under EPCA, including residential clothes washers. 76 FR 12422. These regulations for residential clothes washers are codified in 10 CFR 429.20.

The certification requirements for residential clothes washers consist of a sampling plan for selection of units for testing and requirements for certification reports. In the August 2011 SNOPR, DOE proposed amending the provisions in the sampling plan in 10 CFR part 429.20(a)(2) that would include IMEF along with the existing measure of MEF, and IWF along with the existing measure of WF.

AHAM and ALS expressed support for DOE's proposal to include IMEF and IWF along with the existing measures of MEF and WF, respectively in the sampling plan in 10 CFR 429.20(a)(2). AHAM also supported DOE's proposal to not make any changes to the reporting requirements for residential clothes washers. (AHAM, No. 24 at p. 6; ALS, No. 22 at p. 4)

In the November 2011 SNOPR, DOE proposed amending the reporting requirements in 10 CFR 429.20(b)(2) to require manufacturers, when using appendix J2, to list all cycle settings comprising the complete energy test cycle for each basic model. As described previously in section III.C.4.f, DOE does not intend to make this information publicly available as part of the certification report.

Today's final rule modifies the reporting requirements in 10 CFR 429.20(b)(2) by specifying that a certification report shall include publicly available information including MEF, WF, and capacity; as well as the list of cycle settings comprising the complete energy test cycle for each basic model, which would not be made publicly available as part of the report. The requirement to provide the list of cycle settings comprising the complete energy test cycle will apply only to test results obtained using appendix J2.

H. Impacts of the Test Procedure Amendments on EnergyGuide and ENERGYSTAR

In the September 2010 NOPR, DOE determined that the proposed test procedure amendments would not affect the FTC EnergyGuide labeling program because DOE did not propose to amend the estimated annual operating cost calculation in 10 CFR 430.23. DOE received multiple comments on the impacts of test procedure amendments on the EnergyGuide and ENERGYSTAR programs.

In the August 2011 SNOPR, DOE addressed comments related to EnergyGuide impacts. DOE also received the following comment regarding impacts to the ENERGYSTAR program. NEEA stated that the ENERGYSTAR program has weathered a number of standards changes for the products promoted under its brand, and has periodically updated its program specifications in response to these changes. (NEEA, No. 12 at p. 16) DOE agrees that the ENERGYSTAR program periodically updates its program specifications for each product in response to changes in efficiency standards, as well as changes in the availability of products on the market. Therefore, DOE expects that the ENERGYSTAR program will be able to modify its program specifications for clothes washers to incorporate the integrated efficiency metrics after the compliance date of any amended standards for clothes washers.

In the August 2011 SNOPR, DOE proposed to amend the estimated annual operating cost by incorporating the cost of energy consumed in the non-active washing modes. DOE also proposed to update the number of annual use cycles, which would affect the estimated annual operating cost disclosed on the EnergyGuide label. DOE received several comments related to its proposal to update the annual operating cost, as described previously in section III.D.

For the reasons described in section III.D and the August 2011 SNOPR, today's final rule amends the estimated annual operating cost by incorporating the cost of energy consumed in the non-active wash modes. Today's final rule also updates the annual use cycles, which affects the estimated annual operating cost. Pursuant to 42 U.S.C. 6294, the FTC may revise the EnergyGuide label for residential clothes washers.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget has determined that test procedure rulemakings do not constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *www.gc.doe.gov*.

DOE reviewed today's rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE has concluded that the rule would not have a significant impact on a substantial number of small entities. The factual basis for this certification is as follows:

The Small Business Administration (SBA) considers a business entity to be small business, if, together with its affiliates, it employs less than a threshold number of workers specified in 13 CFR part 121. These size standards and codes are established by the North American Industry Classification System (NAICS). The threshold number for NAICS classification code 335224, which applies to household laundry equipment manufacturers and includes clothes washer manufacturers, is 1,000 employees. Searches of the SBA Web site [14] to identify clothes washer manufacturers within these NAICS codes identified, out of approximately 17 manufacturers supplying clothes washers in the United States, one small business. This small business manufactures laundry appliances, including clothes washers. The other manufacturers supplying clothes washers are large multinational corporations.

Today's final rule would amend DOE's test procedure by incorporating testing provisions to address active mode, standby mode, and off mode energy and water consumption that will

[14] A searchable database of certified small businesses is available online at: *http://dsbs.sba.gov/dsbs/search/dsp__dsbs.cfm*.

be used to demonstrate compliance with energy conservation standards. The test procedure amendments for measuring standby and off mode power using the ''alternative method'' involve measuring power input when the clothes washer is in inactive mode or off mode, or both if both modes are available on the clothes washer under test, as a proxy for measuring power consumption in all low-power modes. These tests can be conducted in the same facilities used for the current energy testing of these products, so it is anticipated that manufacturers would not incur any additional facilities costs as a result of the proposed test procedure amendments. The power meter required for these tests might require greater accuracy than the power meter used for current energy testing, but the investment required for a possible instrumentation upgrade is expected to be approximately a few thousand dollars. The duration of each non-active washing mode test period is expected to be roughly 30–45 minutes, depending on stability of the power, using the alternate approach described previously. This is comparable to approximately one-half to two-thirds the time required to conduct a single energy test wash cycle. Each clothes washer tested requires, on average, approximately 15 test cycles for energy testing, which equates to about 3 days of testing. Using the alternate approach adopted in today's final rule, DOE estimates roughly a 3-percent increase in total test period duration. DOE notes that the provisions from IEC Standard 62301 (Second Edition) incorporated by reference in today's final rule would require longer test durations in the event that the threshold stability criteria of the power measurement are not met. However, based on DOE's observations during testing for the September 2010 NOPR and August 2011 SNOPR, the likelihood of such a longer test being required should be small.

DOE also estimates that it currently costs a manufacturer approximately $2300 on average, including the cost of consumables, to conduct energy testing for a particular clothes washer. DOE further estimates that the cost of additional testing for non-active washing modes using the alternate approach adopted in today's final rule will average $75 per machine, a 3 percent increase over current test costs.

DOE does not expect that these additional requirements for equipment and time and additional cost to conduct the non-active washing mode will impose a significant economic burden on entities subject to the applicable testing requirements. Although the small business has significantly lower sales than other manufacturers over which to amortize these additional costs, it produces only a single platform that would be subject to the proposed non-active washing mode tests.

Furthermore, the test procedure amendments for the active washing mode adopted in today's final rule will not increase test burden because they comprise revisions to calculations rather than additional, longer, or more complex methodology.

In response to the August 2011 SNOPR, ALS stated that it takes no position on DOE's tentative conclusion that the September 2010 NOPR and August 2011 SNOPR would not have a significant economic impact on a substantial number of small entities. ALS stated that it needs to conduct a significant number of tests utilizing the proposed test procedure before commenting on the additional burden that falls on manufacturers. (ALS, No. 22 at p. 3).

For the reasons discussed above, DOE concludes and certifies that today's final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE has transmitted the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the SBA for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of residential clothes washers must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for clothes washers, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including residential clothes washers. (76 FR 12422 (March 7, 2011)). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this final rule, DOE amends its test procedure for residential clothes washers. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this rule amends an existing rule without affecting the amount, quality or distribution of energy usage, and, therefore, will not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE examined this final rule and determined that it will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA

governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of today's final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *www.gc.doe.gov*. DOE examined today's final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Today's final rule will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988), that this regulation will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed today's final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

Today's regulatory action is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The amendments to the test procedure in today's final rule incorporate testing

methods contained in the following commercial standards:

1. AATCC Test Method 79–2010, Absorbency of Textiles, Revised 2010.
2. AATCC Test Method 118–2007, Oil Repellency: Hydrocarbon Resistance Test, Revised 2007.
3. AATCC Test Method 135–2010, Dimensional Changes of Fabrics after Home Laundering.
4. IEC Standard 62301, Household electrical appliances—Measurement of standby power, Edition 2.0, 2011–01.

DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA (*i.e.,* whether they were developed in a manner that fully provides for public participation, comment, and review). DOE has consulted with both the Attorney General and the Chairman of the FTC about the impact on using the methods contained in these standards and has received no comments objecting to their use.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of today's rule before its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

N. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects

10 CFR Part 429

Confidential business information, Energy conservation, Household appliances, Imports, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on February 22, 2012.

Kathleen Hogan,

Deputy Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE amends parts 429 and 430 of title 10 of the Code of Federal Regulations, as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 429.20 is amended by:
■ a. Revising paragraph (a)(2)(i) introductory text;
■ b. Revising paragraph (a)(2)(ii) introductory text;
■ c. Adding paragraph (b)(3).

The revisions and addition read as follows:

§ 429.20 Residential clothes washers.

(a) * * *

(2) * * *

(i) Any represented value of the water factor, integrated water factor, the estimated annual operating cost, the energy or water consumption, or other measure of energy or water consumption of a basic model for which consumers would favor lower values shall be greater than or equal to the higher of:

* * * * *

(ii) Any represented value of the modified energy factor, integrated modified energy factor, or other measure of energy or water consumption of a basic model for which consumers would favor higher values shall be less than or equal to the lower of:

* * * * *

(b) * * *

(3) Pursuant to § 429.12(b)(13), a certification report shall include the following additional product-specific information: When using appendix J2, a list of all cycle selections comprising the complete energy test cycle for each basic model.

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 3. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 4. Section 430.3 is amended by:
■ a. Redesignating paragraphs (c) through (o) as paragraphs (d) through (p);
■ b. Adding new paragraph (c);
■ c. Revising newly designated paragraphs (m) introductory text and (m)(2).

The additions and revisions read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(c) *AATCC.* American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, NC 27709, (919) 549–3526, or go to *www.aatcc.org.*

(1) AATCC Test Method 79–2010, Absorbency of Textiles, Revised 2010, IBR approved for Appendix J2 to Subpart B.

(2) AATCC Test Method 118–2007, Oil Repellency: Hydrocarbon Resistance Test, Revised 2007, IBR approved for Appendix J2 to Subpart B.

(3) AATCC Test Method 135–2010, Dimensional Changes of Fabrics after Home Laundering, Revised 2010, IBR approved for Appendix J2 to Subpart B.

* * * * *

(m) *IEC.* International Electrotechnical Commission, available from the American National Standards Institute, 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or go to *http://webstore.ansi.org.*

* * * * *

(2) IEC Standard 62301 (''IEC 62301''), *Household electrical appliances—Measurement of standby power,* Edition 2.0, 2011–01, IBR approved for Appendix J2 to Subpart B.

* * * * *

■ 5. Section 430.23 is amended by revising paragraph (j) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(j) *Clothes washers.* (1) The estimated annual operating cost for automatic and semi-automatic clothes washers must be rounded off to the nearest dollar per year and is defined as follows:

(i) When using appendix J2 (see the note at the beginning of appendix J2),

(A) When electrically heated water is used,

$(N_1 \times E_{TE1} \times C_{KWH})$

Where:

N_1 = the representative average residential clothes washer use of 392 cycles per year according to appendix J1,

E_{TE1} = the total per-cycle energy consumption when electrically heated water is used, in kilowatt-hours per cycle, determined according to section 4.1.7 of appendix J1, and

C_{KWH} = the representative average unit cost, in dollars per kilowatt-hour, as provided by the Secretary.

(B) When gas-heated or oil-heated water is used,

$(N_1 \times ((ME_{T1} \times C_{KWH}) + (HE_{TG1} \times C_{BTU})))$

Where:

N_1 and C_{KWH} are defined in paragraph (j)(1)(i)(A) of this section,

ME_{T1} = the total weighted per-cycle machine electrical energy consumption, in kilowatt-hours per cycle, determined according to section 4.1.6 of appendix J1,

HE_{TG1} = the total per-cycle hot water energy consumption using gas-heated or oil-heated water, in Btu per cycle, determined according to section 4.1.4 of appendix J1, and

C_{BTU} = the representative average unit cost, in dollars per Btu for oil or gas, as appropriate, as provided by the Secretary.

(ii) When using appendix J2,

(A) When electrically heated water is used,

$$(N_2 \times (E_{TE2} + E_{TSO}) \times C_{KWH})$$

Where:

N_2 = the representative average residential clothes washer use of 295 cycles per year according to appendix J2,

E_{TE2} = the total per-cycle energy consumption when electrically heated water is used, in kilowatt-hours per cycle, determined according to section 4.1.7 of appendix J2,

E_{TSO} = the per-cycle combined low-power mode energy consumption, in kilowatt-hours per cycle, determined according to section 4.4 of appendix J2, and

C_{KWH} = the representative average unit cost, in dollars per kilowatt-hour, as provided by the Secretary.

(B) When gas-heated or oil-heated water is used,

$$(N_2 \times ((ME_{T2} + E_{TSO}) \times C_{KWH}) + (HE_{TG2} \times C_{BTU}))$$

Where:

N_2 and E_{TSO} are defined in (j)(1)(ii)(A) of this section,

ME_{T2} = the total weighted per-cycle machine electrical energy consumption, in kilowatt-hours per cycle, determined according to section 4.1.6 of appendix J2,

C_{KWH} = the representative average unit cost, in dollars per kilowatt-hour, as provided by the Secretary,

HE_{TG2} = the total per-cycle hot water energy consumption using gas-heated or oil-heated water, in Btu per cycle, determined according to section 4.1.4 of appendix J2,

C_{BTU} = the representative average unit cost, in dollars per Btu for oil or gas, as appropriate, as provided by the Secretary.

(2)(i) The modified energy factor for automatic and semi-automatic clothes washers is determined according to section 4.4 of appendix J1 (when using appendix J1) and section 4.5 of appendix J2 (when using appendix J2). The result shall be rounded off to the nearest 0.01 cubic foot per kilowatt-hour per cycle.

(ii) The integrated modified energy factor for automatic and semi-automatic clothes washers is determined according to section 4.6 of appendix J2 (when using appendix J2). The result shall be rounded off to the nearest 0.01 cubic foot per kilowatt-hour per cycle.

(3) Other useful measures of energy consumption for automatic or semi-automatic clothes washers shall be those measures of energy consumption which the Secretary determines are likely to assist consumers in making purchasing decisions and which are derived from the application of appendix J1 or appendix J2, as appropriate. In addition, the annual water consumption of a clothes washer can be determined as:

(i) When using appendix J1, the product of the representative average-use of 392 cycles per year and the total weighted per-cycle water consumption in gallons per cycle determined according to section 4.2.2 of appendix J1. The water factor can be determined according to section 4.2.3 of appendix J1, with the result rounded off to the nearest 0.1 gallons per cycle per cubic foot. The remaining moisture content can be determined according to section 3.8 of appendix J1, with the result rounded off to the nearest 0.1 percent.

(ii) When using appendix J2, the product of the representative average-use of 295 cycles per year and the total weighted per-cycle water consumption for all wash cycles, in gallons per cycle, determined according to section 4.2.11 of appendix J2. The water factor can be determined according to section 4.2.12 of appendix J2, with the result rounded off to the nearest 0.1 gallons per cycle per cubic foot. The integrated water factor can be determined according to section 4.2.13 of appendix J2, with the result rounded off to the nearest 0.1 gallons per cycle per cubic foot. The remaining moisture content can be determined according to section 3.8 of appendix J2, with the result rounded off to the nearest 0.1 percent.

* * * * *

Appendix J to Subpart B of Part 430—[Removed]

■ 6. Appendix J to subpart B of part 430 is removed.

Appendix J1—[Amended]

■ 7. Appendix J1 to subpart B of part 430 is amended by:
■ a. Revising the introductory text;
■ b. Revising section 1.19;
■ c. Revising section 1.22;
■ d. Removing sections 2.6.1.1 through 2.6.1.2.4;
■ e. Revising section 2.6.3.1;
■ f. Revising section 2.6.4.3
■ g. Revising section 2.6.4.5.3(b);
■ h. Revising section 2.6.6.1;
■ i. Revising section 2.6.6.2;
■ j. Revising section 2.10;
■ k. Revising section 3.6;
■ l. Revising section 4.1.4;
■ m. Revising section 4.2;
■ n. Revising section 4.2.3;
■ o. Removing section 4.5;
■ p. Revising section 5; and
■ q. Revising section 6.2.

The revisions read as follows:

Appendix J1 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Automatic and Semi-Automatic Clothes Washers

Manufacturers may use Appendix J1 to certify compliance with existing DOE energy conservation standards until the compliance date of any amended standards that address standby and off mode power consumption for residential clothes washers. After this date, all residential clothes washers shall be tested using the provisions of Appendix J2.

* * * * *

1.19 *Water factor* means the quotient of the total weighted per-cycle water consumption divided by the cubic foot (or liter) capacity of the clothes washer.

* * * * *

1.22 *Cold rinse* means the coldest rinse temperature available on the machine.

* * * * *

2.6.3.1 Perform 5 complete normal wash-rinse-spin cycles, the first two with current AHAM Standard detergent Formula 3 and the last three without detergent. Place the test cloth in a clothes washer set at the maximum water level. Wash the load for ten minutes in soft water (17 ppm hardness or less) using 27.0 grams + 4.0 grams per pound of cloth load of AHAM Standard detergent Formula 3. The wash temperature is to be controlled to 135 °F ± 5 °F (57.2 °C ± 2.8 °C) and the rinse temperature is to be controlled to 60 °F ± 5 °F (15.6 °C ± 2.8 °C). Repeat the cycle with detergent and then repeat the cycle three additional times without detergent, bone drying the load between cycles (total of five wash and rinse cycles).

* * * * *

2.6.4.3 The thread count shall be 65 × 57 per inch (warp × fill), ±2 percent.

* * * * *

2.6.4.5.3. * * *

(b) Copies of the above standards incorporated by reference can be obtained from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, NC 27709, telephone (919) 549–3526, fax (919) 549–8933, or email: *orders@aatcc.org*.

* * * * *

2.6.6.1 Average the values of 3 test runs and fill in Table 2.6.5 of this appendix. Perform a linear least-squares fit to determine coefficients A and B such that the standard RMC values shown in Table 2.6.6.1 of this appendix ($RMC_{standard}$) are linearly related to the RMC values measured in section 2.6.5 of this appendix (RMC_{cloth}):

$$RMC_{standard} \sim A * RMC_{cloth} + B$$

where A and B are coefficients of the linear least-squares fit.

* * * * *

2.6.6.2 Perform an analysis of variance with replication test using two factors, spin

speed and lot, to check the interaction of speed and lot. Use the values from Table 2.6.5 and Table 2.6.6.1 of this Appendix in the calculation. The ''P'' value of the F-statistic for interaction between spin speed and lot in the variance analysis shall be greater than or equal to 0.1. If the ''P'' value is less than 0.1, the test cloth is unacceptable. ''P'' is a theoretically based measure of interaction based on an analysis of variance.

* * * * *

2.10 *Wash time setting.* If one wash time is prescribed in the energy test cycle, that shall be the wash time setting; otherwise, the wash time setting shall be the higher of either the minimum or 70 percent of the maximum wash time available in the energy test cycle, regardless of the labeling of suggested dial locations. If the clothes washer is equipped with an electromechanical dial controlling wash time, reset the dial to the minimum wash time and then turn it in the direction of increasing wash time to reach the appropriate setting. If the appropriate setting is passed, return the dial to the minimum wash time and then turn in the direction of increasing wash time until the setting is reached.

* * * * *

3.6 *''Cold Wash'' (Minimum Wash Temperature Selection).* Water and electrical energy consumption shall be measured for each water fill level or test load size as specified in sections 3.6.1 through 3.6.3 of this Appendix for the coldest wash temperature selection available. For a clothes washer that offers two or more wash temperature settings labeled as cold, such as ''Cold'' and ''Tap Cold'', the setting with the minimum wash temperature shall be considered the cold wash. If any of the other cold wash temperature settings add hot water to raise the wash temperature above the cold water supply temperature, as defined in section 2.3 of this Appendix, those setting(s) shall be considered warm wash setting(s), as defined in section 1.18 of this Appendix. If none of the cold wash temperature settings add hot water for any of the water fill levels or test load sizes required for the energy test cycle, the wash temperature setting labeled as ''Cold'' shall be considered the cold wash, and the other wash temperature setting(s) labeled as cold shall not be required for testing.

* * * * *

4.1.4 *Total per-cycle hot water energy consumption using gas-heated or oil-heated water.* Calculate for the energy test cycle the per-cycle hot water consumption, HE_{TG}, using gas-heated or oil-heated water, expressed in Btu per cycle (or megajoules per cycle) and defined as:

$HE_{TG} = HE_T \times 1/e \times 3412$ Btu/kWh or
$HE_{TG} = HE_T \times 1/e \times 3.6$ MJ/kWh

Where:

e = Nominal gas or oil water heater efficiency=0.75.

HE_T = As defined in 4.1.3.

* * * * *

4.2.3 *Water factor.* Calculate the water factor, WF, expressed in gallons per cycle per cubic foot (or liters per cycle per liter), as:

$WF = Q_T/C$

Where:

Q_T = As defined in section 4.2.2.

C = As defined in section 3.1.5.

* * * * *

5. Test Loads

TABLE 5.1—TEST LOAD SIZES

Container volume		Minimum load		Maximum load		Average load	
cu. ft. ≥ <	liter ≥ <	lb	kg	lb	kg	lb	kg
0–0.80	0–22.7	3.00	1.36	3.00	1.36	3.00	1.36
0.80–0.90	22.7–25.5	3.00	1.36	3.50	1.59	3.25	1.47
0.90–1.00	25.5–28.3	3.00	1.36	3.90	1.77	3.45	1.56
1.00–1.10	28.3–31.1	3.00	1.36	4.30	1.95	3.65	1.66
1.10–1.20	31.1–34.0	3.00	1.36	4.70	2.13	3.85	1.75
1.20–1.30	34.0–36.8	3.00	1.36	5.10	2.31	4.05	1.84
1.30–1.40	36.8–39.6	3.00	1.36	5.50	2.49	4.25	1.93
1.40–1.50	39.6–42.5	3.00	1.36	5.90	2.68	4.45	2.02
1.50–1.60	42.5–45.3	3.00	1.36	6.40	2.90	4.70	2.13
1.60–1.70	45.3–48.1	3.00	1.36	6.80	3.08	4.90	2.22
1.70–1.80	48.1–51.0	3.00	1.36	7.20	3.27	5.10	2.31
1.80–1.90	51.0–53.8	3.00	1.36	7.60	3.45	5.30	2.40
1.90–2.00	53.8–56.6	3.00	1.36	8.00	3.63	5.50	2.49
2.00–2.10	56.6–59.5	3.00	1.36	8.40	3.81	5.70	2.59
2.10–2.20	59.5–62.3	3.00	1.36	8.80	3.99	5.90	2.68
2.20–2.30	62.3–65.1	3.00	1.36	9.20	4.17	6.10	2.77
2.30–2.40	65.1–68.0	3.00	1.36	9.60	4.35	6.30	2.86
2.40–2.50	68.0–70.8	3.00	1.36	10.00	4.54	6.50	2.95
2.50–2.60	70.8–73.6	3.00	1.36	10.50	4.76	6.75	3.06
2.60–2.70	73.6–76.5	3.00	1.36	10.90	4.94	6.95	3.15
2.70–2.80	76.5–79.3	3.00	1.36	11.30	5.13	7.15	3.24
2.80–2.90	79.3–82.1	3.00	1.36	11.70	5.31	7.35	3.33
2.90–3.00	82.1–85.0	3.00	1.36	12.10	5.49	7.55	3.42
3.00–3.10	85.0–87.8	3.00	1.36	12.50	5.67	7.75	3.52
3.10–3.20	87.8–90.6	3.00	1.36	12.90	5.85	7.95	3.61
3.20–3.30	90.6–93.4	3.00	1.36	13.30	6.03	8.15	3.70
3.30–3.40	93.4–96.3	3.00	1.36	13.70	6.21	8.35	3.79
3.40–3.50	96.3–99.1	3.00	1.36	14.10	6.40	8.55	3.88
3.50–3.60	99.1–101.9	3.00	1.36	14.60	6.62	8.80	3.99
3.60–3.70	101.9–104.8	3.00	1.36	15.00	6.80	9.00	4.08
3.70–3.80	104.8–107.6	3.00	1.36	15.40	6.99	9.20	4.17
3.80–3.90	107.6–110.4	3.00	1.36	15.80	7.16	9.40	4.26
3.90–4.00	110.4–113.3	3.00	1.36	16.20	7.34	9.60	4.35
4.00–4.10	113.3–116.1	3.00	1.36	16.60	7.53	9.80	4.45
4.10–4.20	116.1–118.9	3.00	1.36	17.00	7.72	10.00	4.54
4.20–4.30	118.9–121.8	3.00	1.36	17.40	7.90	10.20	4.63
4.30–4.40	121.8–124.6	3.00	1.36	17.80	8.09	10.40	4.72
4.40–4.50	124.6–127.4	3.00	1.36	18.20	8.27	10.60	4.82
4.50–4.60	127.4–130.3	3.00	1.36	18.70	8.46	10.85	4.91
4.60–4.70	130.3–133.1	3.00	1.36	19.10	8.65	11.05	5.00

TABLE 5.1—TEST LOAD SIZES—Continued

Container volume		Minimum load		Maximum load		Average load	
cu. ft. ≥ <	liter ≥ <	lb	kg	lb	kg	lb	kg
4.70–4.80	133.1–135.9	3.00	1.36	19.50	8.83	11.25	5.10
4.80–4.90	135.9–138.8	3.00	1.36	19.90	9.02	11.45	5.19
4.90–5.00	138.8–141.6	3.00	1.36	20.30	9.20	11.65	5.28
5.00–5.10	141.6–144.4	3.00	1.36	20.70	9.39	11.85	5.38
5.10–5.20	144.4–147.2	3.00	1.36	21.10	9.58	12.05	5.47
5.20–5.30	147.2–150.1	3.00	1.36	21.50	9.76	12.25	5.56
5.30–5.40	150.1–152.9	3.00	1.36	21.90	9.95	12.45	5.65
5.40–5.50	152.9–155.7	3.00	1.36	22.30	10.13	12.65	5.75
5.50–5.60	155.7–158.6	3.00	1.36	22.80	10.32	12.90	5.84
5.60–5.70	158.6–161.4	3.00	1.36	23.20	10.51	13.10	5.93
5.70–5.80	161.4–164.2	3.00	1.36	23.60	10.69	13.30	6.03
5.80–5.90	164.2–167.1	3.00	1.36	24.00	10.88	13.50	6.12
5.90–6.00	167.1–169.9	3.00	1.36	24.40	11.06	13.70	6.21

Notes: (1) All test load weights are bone dry weights.
(2) Allowable tolerance on the test load weights are ±0.10 lbs (0.05 kg).

* * * * *

6.2 *Nonconventional Wash System Energy Consumption Test.* The field test may consist of a minimum of 10 of the nonconventional clothes washers (''test clothes washers'') and 10 clothes washers already being distributed in commerce (''base clothes washers''). The tests should include a minimum of 50 energy test cycles per clothes washer. The test clothes washers and base clothes washers should be identical in construction except for the controls or systems being tested. Equal numbers of both the test clothes washer and the base clothes washer should be tested simultaneously in comparable settings to minimize seasonal or consumer laundering conditions or variations. The clothes washers should be monitored in such a way as to accurately record the average total energy and water consumption per cycle, including water heating energy when electrically heated water is used, and the energy required to remove the remaining moisture of the test load. The field test results should be used to determine the best method to correlate the rating of the test clothes washer to the rating of the base clothes washer.

* * * * *

■ 6. Add a new Appendix J2 to subpart B of part 430 to read as follows:

Appendix J2 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Automatic and Semi-Automatic Clothes Washers

Manufacturers may use Appendix J1 to certify compliance with existing DOE energy conservation standards until the compliance date of any amended standards that address standby and off mode power consumption for residential clothes washers. After this date, all residential clothes washers shall be tested using the provisions of Appendix J2.

1. Definitions and Symbols

1.1 *Active mode* means a mode in which the clothes washer is connected to a mains power source, has been activated, and is performing one or more of the main functions of washing, soaking, tumbling, agitating, rinsing, and/or removing water from the clothing, or is involved in functions necessary for these main functions, such as admitting water into the washer or pumping water out of the washer. Active mode also includes delay start and cycle finished modes.

1.2 *Active washing mode* means a mode in which the clothes washer is performing any of the operations included in a complete cycle intended for washing a clothing load, including the main functions of washing, soaking, tumbling, agitating, rinsing, and/or removing water from the clothing.

1.3 *Adaptive control system* means a clothes washer control system, other than an adaptive water fill control system, which is capable of automatically adjusting washer operation or washing conditions based on characteristics of the clothes load placed in the clothes container, without allowing or requiring consumer intervention or actions. The automatic adjustments may, for example, include automatic selection, modification, or control of any of the following: Wash water temperature, agitation or tumble cycle time, number of rinse cycles, and spin speed. The characteristics of the clothes load, which could trigger such adjustments, could, for example, consist of or be indicated by the presence of either soil, soap, suds, or any other additive laundering substitute or complementary product.

NOTE: Appendix J2 does not provide a means for determining the energy consumption of a clothes washer with an adaptive control system. A waiver must be obtained pursuant to 10 CFR 430.27 to establish an acceptable test procedure for each such clothes washer.

1.4 *Adaptive water fill control system* means a clothes washer water fill control system which is capable of automatically adjusting the water fill level based on the size or weight of the clothes load placed in the clothes container, without allowing or requiring consumer intervention or actions.

1.5 *Bone-dry* means a condition of a load of test cloth which has been dried in a dryer at maximum temperature for a minimum of 10 minutes, removed and weighed before cool down, and then dried again for 10 minute periods until the final weight change of the load is 1 percent or less.

1.6 *Clothes container* means the compartment within the clothes washer that holds the clothes during the operation of the machine.

1.7 *Cold rinse* means the coldest rinse temperature available on the machine.

1.8 *Combined low-power mode* means the aggregate of available modes other than active washing mode, including inactive mode, off mode, delay start mode, and cycle finished mode.

1.9 *Compact* means a clothes washer which has a clothes container capacity of less than 1.6 ft^3 (45 L).

1.10 *Cycle finished mode* means an active mode which provides continuous status display, intermittent tumbling, or air circulation following operation in active washing mode.

1.11 *Deep rinse cycle* means a rinse cycle in which the clothes container is filled with water to a selected level and the clothes load is rinsed by agitating it or tumbling it through the water.

1.12 *Delay start mode* means an active mode in which activation of active washing mode is facilitated by a timer.

1.13 *Energy test cycle* for a basic model means:

(A) The cycle selection recommended by the manufacturer for washing cotton or linen clothes, and includes all wash/rinse temperature selections for each of the temperature use factors (TUFs) offered in that cycle, and

(B) If the cycle selection described in Part (A) does not include all wash/rinse temperature selections for each of the TUFs available on the clothes washer, the energy test cycle shall include, in addition to Part (A), the alternate cycle selection(s) offering these remaining wash/rinse temperature selection(s), tested only at the wash/rinse temperature selection(s) for each TUF not available on the cycle selection described in Part (A).

Where multiple alternate cycle selections offer a wash/rinse temperature selection for which a TUF has been developed, and that is not available on the cycle selection

recommended by the manufacturer for washing cotton or linen clothes described in Part (A), the alternate cycle selection certified by the manufacturer to have the highest energy consumption for that TUF, as measured according to section 2.13, shall be included in the energy test cycle, so that each TUF that is available on the clothes washer has been tested once.

(C) All cycle selections included under Part (A) and all cycle selections included under Part (B) shall be tested using each appropriate load size as defined in section 2.8 and Table 5.1 of this appendix.

(D) For any cycle selection tested under (A) or (B), the manufacturer default settings shall be used, except for the temperature selection, if necessary. This includes wash conditions such as agitation/tumble operation, soil level, spin speed(s), wash times, rinse times, and all other wash parameters or optional features applicable to that cycle, including water heating time for water heating clothes washers.

(E) Each wash cycle included as part of the energy test cycle shall include the entire active washing mode and exclude any delay start or cycle finished modes.

(F) The energy test cycle shall not include any cycle, if available, that is dedicated for cleaning, deodorizing, or sanitizing the clothes washer, and is separate from clothes washing cycles.

1.14 *IEC 62301* means the test standard published by the International Electrotechnical Commission, entitled ''Household electrical appliances–Measurement of standby power,'' Publication 62301, Edition 2.0 2011–01 (incorporated by reference; see § 430.3).

1.15 *Inactive mode* means a standby mode that facilitates the activation of active mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display.

1.16 *Integrated modified energy factor* means the quotient of the cubic foot (or liter) capacity of the clothes container divided by the total clothes washer energy consumption per cycle, with such energy consumption expressed as the sum of:

(a) The machine electrical energy consumption;

(b) The hot water energy consumption;

(c) The energy required for removal of the remaining moisture in the wash load; and

(d) The combined low-power mode energy consumption.

1.17 *Integrated water factor* means the quotient of the total weighted per-cycle water consumption for all wash cycles in gallons divided by the cubic foot (or liter) capacity of the clothes washer.

1.18 *Load usage factor* means the percentage of the total number of wash loads that a user would wash a particular size (weight) load.

1.19 *Lot* means a quantity of cloth that has been manufactured with the same batches of cotton and polyester during one continuous process.

1.20 *Manual control system* means a clothes washer control system which requires that the consumer make the choices that determine washer operation or washing conditions, such as, for example, wash/rinse temperature selections and wash time, before starting the cycle.

1.21 *Manual water fill control system* means a clothes washer water fill control system which requires the consumer to determine or select the water fill level.

1.22 *Modified energy factor* means the quotient of the cubic foot (or liter) capacity of the clothes container divided by the total clothes washer energy consumption per cycle, with such energy consumption expressed as the sum of the machine electrical energy consumption, the hot water energy consumption, and the energy required for removal of the remaining moisture in the wash load.

1.23 *Non-water-heating clothes washer* means a clothes washer which does not have an internal water heating device to generate hot water.

1.24 *Off mode* means a mode in which the clothes washer is connected to a mains power source and is not providing any active or standby mode function, and where the mode may persist for an indefinite time. An indicator that only shows the user that the product is in the off position is included within the classification of an off mode.

1.25 *Roll* means a subset of a lot.

1.26 *Spray rinse cycle* means a rinse cycle in which water is sprayed onto the clothes for a period of time without maintaining any specific water level in the clothes container.

1.27 *Standard* means a clothes washer which has a clothes container capacity of 1.6 ft^3 (45 L) or greater.

1.28 *Standby mode* means any mode in which the clothes washer is connected to a mains power source and offers one or more of the following user oriented or protective functions that may persist for an indefinite time:

(a) To facilitate the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer;

(b) Continuous functions, including information or status displays (including clocks) or sensor-based functions.

A timer is a continuous clock function (which may or may not be associated with a display) that provides regular scheduled tasks (*e.g.,* switching) and that operates on a continuous basis.

1.29 *Symbol usage.* The following identity relationships are provided to help clarify the symbology used throughout this procedure.

C—Capacity
C (with subscripts)—Cold Water Consumption
D—Energy Consumption for Removal of Moisture from Test Load
E—Electrical Energy Consumption
F—Load Usage Factor
H—Hot Water Consumption
HE—Hot Water Energy Consumption
ME—Machine Electrical Energy Consumption
P—Power
Q—Water Consumption
RMC—Remaining Moisture Content
S—Annual Hours
TUF—Temperature Use Factor
V—Temperature-Weighted Hot Water Consumption
W—Mass of Water
WC—Weight of Test Load After Extraction
WI—Initial Weight of Dry Test Load

Subscripts:

a or avg—Average Test Load
B—Part B of the Energy Test Cycle
c—Cold Wash (minimum wash temp.)
corr—Corrected (RMC values)
h—Hot Wash (maximum wash temp. ≤135 °F (57.2 °C))
ia—Inactive Mode
LP—Combined Low-Power Mode
m—Extra Hot Wash (maximum wash temp. >135 °F (57.2 °C))
n—Minimum Test Load
o—Off Mode
oi—Combined Off and Inactive Modes
T—Total
w—Warm Wash
ww—Warm Wash/Warm Rinse
x—Maximum Test Load

The following examples are provided to show how the above symbols can be used to define variables:

Em_x = ''Electrical Energy Consumption'' for an ''Extra Hot Wash'' and ''Maximum Test Load''
HE_{min} = ''Hot Water Energy Consumption'' for the ''Minimum Test Load''
P_{ia} = ''Power'' in ''Inactive Mode''
Qh_{min} = ''Water Consumption'' for a ''Hot Wash'' and ''Minimum Test Load''
TUF_m = ''Temperature Use Factor'' for an ''Extra Hot Wash''

1.30 *Temperature use factor* means, for a particular wash/rinse temperature setting, the percentage of the total number of wash loads that an average user would wash with that setting.

1.31 *Thermostatically controlled water valves* means clothes washer controls that have the ability to sense and adjust the hot and cold supply water.

1.32 *Uniformly distributed warm wash temperature selection(s)* means (A) multiple warm wash selections for which the warm wash water temperatures have a linear relationship with all discrete warm wash selections when the water temperatures are plotted against equally spaced consecutive warm wash selections between the hottest warm wash and the coldest warm wash. If the warm wash has infinite selections, the warm wash water temperature has a linear relationship with the distance on the selection device (*e.g.* dial angle or slide movement) between the hottest warm wash and the coldest warm wash. The criteria for a linear relationship as specified above is that the difference between the actual water temperature at any warm wash selection and the point where that temperature is depicted on the temperature/selection line formed by connecting the warmest and the coldest warm selections is less than ±5 percent. In all cases, the mean water temperature of the warmest and the coldest warm selections must coincide with the mean of the ''hot wash'' (maximum wash temperature ≤135 °F (57.2 °C)) and ''cold wash'' (minimum wash temperature) water temperatures within ±3.8 °F (±2.1 °C); or (B) on a clothes washer with only one warm wash temperature selection, a warm wash temperature selection with a water temperature that coincides with

the mean of the ''hot wash'' (maximum wash temperature ≤135 °F (57.2 °C)) and ''cold wash'' (minimum wash temperature) water temperatures within ±3.8 °F (±2.1 °C).

1.33 *Warm rinse* means the hottest rinse temperature available on the machine.

1.34 *Warm wash* means all wash temperature selections that are below the maximum wash temperature ≤135 °F (57.2 °C) and above the minimum wash temperature.

1.35 *Water factor* means the quotient of the total weighted per-cycle water consumption for cold wash divided by the cubic foot (or liter) capacity of the clothes washer.

1.36 *Water-heating clothes washer* means a clothes washer where some or all of the hot water for clothes washing is generated by a water heating device internal to the clothes washer.

2. Testing Conditions

2.1 *Installation.* Install the clothes washer in accordance with manufacturer's instructions. For combined low-power mode testing, the product shall be installed in accordance with Section 5, Paragraph 5.2 of IEC 62301 (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes.

2.2 *Electrical energy supply.*

2.2.1 *Supply voltage and frequency.* Maintain the electrical supply at the clothes washer terminal block within 2 percent of 120, 120/240, or 120/208Y volts as applicable to the particular terminal block wiring system and within 2 percent of the nameplate frequency as specified by the manufacturer. If the clothes washer has a dual voltage conversion capability, conduct test at the highest voltage specified by the manufacturer.

2.2.2 *Supply voltage waveform.* For the combined low-power mode testing, maintain the electrical supply voltage waveform indicated in Section 4, Paragraph 4.3.2 of IEC 62301. If the power measuring instrument used for testing is unable to measure and record the total harmonic content during the test measurement period, it is acceptable to measure and record the total harmonic content immediately before and after the test measurement period.

2.3 *Supply Water.*

2.3.1 *Clothes washers in which electrical energy consumption or water energy consumption are affected by the inlet water temperature. (For example, water heating clothes washers or clothes washers with thermostatically controlled water valves.).* The temperature of the hot water supply at the water inlets shall not exceed 135 °F (57.2 °C) and the cold water supply at the water inlets shall not exceed 60 °F (15.6 °C). A water meter shall be installed in both the hot and cold water lines to measure water consumption.

2.3.2 *Clothes washers in which electrical energy consumption and water energy consumption are not affected by the inlet water temperature.* The temperature of the hot water supply shall be maintained at 135 °F ± 5 °F (57.2 °C ± 2.8 °C) and the cold water supply shall be maintained at 60 °F ± 5 °F (15.6 °C ± 2.8 °C). A water meter shall be installed in both the hot and cold water lines to measure water consumption.

2.4 *Water pressure.* The static water pressure at the hot and cold water inlet connection of the clothes washer shall be maintained at 35 pounds per square inch gauge (psig) ±2.5 psig (241.3 kPa ±17.2 kPa) when the water is flowing. The static water pressure for a single water inlet connection shall be maintained at 35 psig ±2.5 psig (241.3 kPa ±17.2 kPa) when the water is flowing. A water pressure gauge shall be installed in both the hot and cold water lines to measure water pressure.

2.5 *Instrumentation.* Perform all test measurements using the following instruments, as appropriate:

2.5.1 *Weighing scales.*

2.5.1.1 *Weighing scale for test cloth.* The scale shall have a resolution of no larger than 0.2 oz (5.7 g) and a maximum error no greater than 0.3 percent of the measured value.

2.5.1.2 *Weighing scale for clothes container capacity measurement.* The scale should have a resolution no larger than 0.50 lbs (0.23 kg) and a maximum error no greater than 0.5 percent of the measured value.

2.5.2 *Watt-hour meter.* The watt-hour meter shall have a resolution no larger than 1 Wh (3.6 kJ) and a maximum error no greater than 2 percent of the measured value for any demand greater than 50 Wh (180.0 kJ).

2.5.3 *Watt meter.* The watt meter used to measure combined low-power mode power consumption shall comply with the requirements specified in Section 4, Paragraph 4.4 of IEC 62301. If the power measuring instrument used for testing is unable to measure and record the crest factor, power factor, or maximum current ratio during the test measurement period, it is acceptable to measure and record the crest factor, power factor, and maximum current ratio immediately before and after the test measurement period.

2.5.4 *Temperature measuring device.* The device shall have an error no greater than ±1 °F (±0.6 °C) over the range being measured.

2.5.5 *Water meter.* The water meter shall have a resolution no larger than 0.1 gallons (0.4 liters) and a maximum error no greater than 2 percent for the water flow rates being measured.

2.5.6 *Water pressure gauge.* The water pressure gauge shall have a resolution of 1 pound per square inch gauge (psig) (6.9 kPa) and shall have an error no greater than 5 percent of any measured value.

2.6 *Test cloths.*

2.6.1 *Energy Test Cloth.* The energy test cloth shall be made from energy test cloth material, as specified in section 2.6.4 of this Appendix, that is 24 ± ½ inches by 36 ± ½ inches (61.0 ± 1.3 cm by 91.4 ± 1.3 cm) and has been hemmed to 22 ± ½ inches by 34 ± ½ inches (55.9 ± 1.3 cm by 86.4 ± 1.3 cm) before washing. The energy test cloth shall be clean and shall not be used for more than 60 test runs (after preconditioning as specified in 2.6.3 of this appendix). All energy test cloth must be permanently marked identifying the lot number of the material. Mixed lots of material shall not be used for testing a clothes washer.

2.6.2 *Energy Stuffer Cloth.* The energy stuffer cloth shall be made from energy test cloth material, as specified in section 2.6.4 of this Appendix, and shall consist of pieces of material that are 12 ± ¼ inches by 12 ± ¼ inches (30.5 ± 0.6 cm by 30.5 ± 0.6 cm) and have been hemmed to 10 ± ¼ inches by 10 ± ¼ inches (25.4 ± 0.6 cm by 25.4 ± 0.6 cm) before washing. The energy stuffer cloth shall be clean and shall not be used for more than 60 test runs (after preconditioning as specified in section 2.6.3 of this Appendix). All energy stuffer cloth must be permanently marked identifying the lot number of the material. Mixed lots of material shall not be used for testing a clothes washer.

2.6.3 *Preconditioning of Test Cloths.* The new test cloths, including energy test cloths and energy stuffer cloths, shall be pre-conditioned in a clothes washer in the following manner:

2.6.3.1 Perform 5 complete normal wash-rinse-spin cycles, the first two with AHAM Standard detergent Formula 3 and the last three without detergent. Place the test cloth in a clothes washer set at the maximum water level. Wash the load for ten minutes with a minimum fill of 20 gallons of soft water (17 ppm hardness or less) using 27.0 grams + 4.0 grams per pound of cloth load of AHAM Standard detergent Formula 3. The wash temperature is to be controlled to 135 °F ± 5°F (57.2 °C ± 2.8 °C) and the rinse temperature is to be controlled to 60°F ± 5°F (15.6 °C ± 2.8 °C). Repeat the cycle with detergent and then repeat the cycle three additional times without detergent, bone drying the load between cycles (total of five wash and rinse cycles).

2.6.4 *Energy test cloth material.* The energy test cloths and energy stuffer cloths shall be made from fabric meeting the following specifications. The material should come from a roll of material with a width of approximately 63 inches and approximately 500 yards per roll. However, other sizes may be used if they fall within the specifications.

2.6.4.1 *Nominal fabric type.* Pure finished bleached cloth made with a momie or granite weave, which is nominally 50 percent cotton and 50 percent polyester.

2.6.4.2 The fabric weight specification shall be 5.60 ± 0.25 ounces per square yard (190.0 ± 8.4 g/m^2).

2.6.4.3 The thread count shall be 65 × 57 per inch (warp × fill), ±2 percent.

2.6.4.4 The warp yarn and filling yarn shall each have fiber content of 50 percent ±4 percent cotton, with the balance being polyester, and be open end spun, 15/1 ±5 percent cotton count blended yarn.

2.6.4.5 Water repellent finishes, such as fluoropolymer stain resistant finishes shall not be applied to the test cloth. The absence of such finishes shall be verified by:

2.6.4.5.1 AATCC Test Method 118–2007, (incorporated by reference; see § 430.3), for each new lot of test cloth (when purchased from the mill) to confirm the absence of Scotchguard ™ or other water repellent finish (required scores of ''D'' across the board).

2.6.4.5.2 AATCC Test Method 79–2010, (incorporated by reference; see § 430.3), for each new lot of test cloth (when purchased from the mill) to confirm the absence of

Scotchguard™ or other water repellent finish (time to absorb one drop should be on the order of 1 second).

2.6.4.6 The moisture absorption and retention shall be evaluated for each new lot of test cloth by the Standard Extractor Remaining Moisture Content (RMC) Test specified in section 2.6.5 of this Appendix.

2.6.4.6.1 Repeat the Standard Extractor RMC Test in section 2.6.5 of this Appendix three times.

2.6.4.6.2 An RMC correction curve shall be calculated as specified in section 2.6.6 of this Appendix.

2.6.4.7 The maximum shrinkage after preconditioning shall not be more than 5 percent of the length and width. Measure per AATCC Test Method 135–2010, (incorporated by reference; see § 430.3).

2.6.5 *Standard Extractor RMC Test Procedure.* The following procedure is used to evaluate the moisture absorption and retention characteristics of a lot of test cloth by measuring the RMC in a standard extractor at a specified set of conditions. Table 2.6.5 of this Appendix is the matrix of test conditions. In the table, ''g Force'' represents units of gravitational acceleration. When this matrix is repeated 3 times, a total of 60 extractor RMC test runs are required. For the purpose of the extractor RMC test, the test cloths may be used for up to 60 test runs (after preconditioning as specified in section 2.6.3 of this Appendix).

TABLE 2.6.5—MATRIX OF EXTRACTOR RMC TEST CONDITIONS

''g Force''	Warm soak		Cold soak	
	15 min. spin	4 min. spin	15 min. spin	4 min. spin
100				
200				
350				
500				
650				

2.6.5.1 The standard extractor RMC tests shall be run in a North Star Engineered Products Inc. (formerly Bock) Model 215 extractor (having a basket diameter of 20 inches, height of 11.5 inches, and volume of 2.09 ft^3), with a variable speed drive (North Star Engineered Products, P.O. Box 5127, Toledo, OH 43611) or an equivalent extractor with same basket design (*i.e.* diameter, height, volume, and hole configuration) and variable speed drive. Table 2.6.5.1 shows the extractor spin speed, in revolutions per minute (RPM), that shall be used to attain each required g-force level.

TABLE 2.6.5.1—EXTRACTOR SPIN SPEEDS FOR EACH TEST CONDITION

''g Force''	RPM
100	594 ± 1
200	840 ± 1
350	1111 ± 1
500	1328 ± 1
650	1514 ± 1

2.6.5.2 *Test Load.* Test loads shall be comprised of randomly selected cloth at the beginning, middle and end of a lot. Test cloths shall be preconditioned in accordance with section 2.6.3 of this Appendix. The load size shall be 8.4 lbs. It is acceptable to use two test loads for standard extractor RMC tests, with each load used for half of the total number of required tests.

2.6.5.3 *Procedure.*

2.6.5.3.1 Using a dryer that complies with the temperature requirements specified in section 2.12 of this Appendix, dry the test cloth until it is ''bone-dry'' according to the definition in section 1.5 of this Appendix. Record the ''bone-dry'' weight of the test load (WI).

2.6.5.3.2 Prepare the test load for soak by grouping four test cloths into loose bundles. Bundles are created by hanging four cloths vertically from one corner and loosely wrapping the test cloth onto itself to form the bundle. Bundles should be wrapped loosely to ensure consistency of water extraction. Bundles are then placed into the water to soak. Eight to nine bundles will be formed depending on the test load. The ninth bundle may not equal four cloths but can incorporate energy stuffer cloths to help offset the size difference.

2.6.5.3.3 Soak the test load for 20 minutes in 10 gallons of soft (<17 ppm) water. The entire test load shall be submerged. The water temperature shall be 100 °F ± 5°F (37.8 °C ± 2.8 °C) at all times between the start and end of the soak.

2.6.5.3.4 Remove the test load and allow each of the test cloth bundles to drain over the water bath for a maximum of 5 seconds.

2.6.5.3.5 Manually place the test cloth bundles in the basket of the extractor, distributing them evenly by eye. The draining and loading process shall take no longer than 1 minute. Spin the load at a fixed speed corresponding to the intended centripetal acceleration level (measured in units of the acceleration of gravity, g) ± 1g for the intended time period ± 5 seconds. The timer shall begin when the extractor meets the required spin speed for each test.

2.6.5.3.6 Record the weight of the test load immediately after the completion of the extractor spin cycle (WC).

2.6.5.3.7 Calculate the remaining moisture content of the test load as (WC–WI)/WI.

2.6.5.3.8 It is not necessary to drain the soak tub if the water bath is corrected for water level and temperature before the next extraction.

2.6.5.3.9 It is not necessary to dry the test load in between extraction runs. However, the bone dry weight shall be checked after every 12 extraction runs to make sure the bone dry weight is within tolerance (8.4 ± 0.1 lb).

2.6.5.3.10 The test load must be soaked and extracted once following bone drying, before continuing with the remaining extraction runs. This extraction shall be performed at the same spin speed used for the extraction run prior to bone drying, for a time period of 4 minutes. Either warm or cold soak temperature may be used.

2.6.5.3.11 The remaining moisture content of the test load shall be measured at five g levels: 100 g, 200 g, 350 g, 500 g, and 650 g, using two different spin times at each g level: 4 minutes and 15 minutes.

2.6.5.4 Repeat section 2.6.5.3 of this Appendix using soft (<17 ppm) water at 60 °F ± 5 °F (15.6 °C ± 2.8 °C).

2.6.6 *Calculation of RMC correction curve.*

2.6.6.1 Average the values of 3 test runs, and fill in Table 2.6.5 of this appendix. Perform a linear least-squares fit to determine coefficients A and B such that the standard RMC values shown in Table 2.6.6.1 of this appendix ($RMC_{standard}$) are linearly related to the RMC values measured in section 2.6.5 of this appendix (RMC_{cloth}):

$$RMC_{standard} \sim A * RMC_{cloth} + B$$

where A and B are coefficients of the linear least-squares fit.

TABLE 2.6.6.1—STANDARD RMC VALUES (RMC STANDARD)

"g Force"	RMC percentage			
	Warm soak		Cold soak	
	15 min. spin (percent)	4 min. spin (percent)	15 min. spin (percent)	4 min. spin (percent)
100	45.9	49.9	49.7	52.8
200	35.7	40.4	37.9	43.1
350	29.6	33.1	30.7	35.8
500	24.2	28.7	25.5	30.0
650	23.0	26.4	24.1	28.0

2.6.6.2 Perform an analysis of variance with replication test using two factors, spin speed and lot, to check the interaction of speed and lot. Use the values from Table 2.6.5 and Table 2.6.6.1 of this Appendix in the calculation. The ''P'' value of the F-statistic for interaction between spin speed and lot in the variance analysis shall be greater than or equal to 0.1. If the ''P'' value is less than 0.1, the test cloth is unacceptable. ''P'' is a theoretically based measure of interaction based on an analysis of variance.

2.6.7 *Application of the RMC correction curve.*

2.6.7.1 Using the coefficients A and B calculated in section 2.6.6.1 of this Appendix:

$RMC_{corr} = A \times RMC + B$

2.6.7.2 Apply this RMC correction curve to measured RMC values in sections 3.8.2.6, 3.8.3.2, and 3.8.3.4 of this Appendix.

2.7 *Test Load Sizes.* Maximum, minimum, and, when required, average test load sizes shall be determined using Table 5.1 of this Appendix and the clothes container capacity as measured in sections 3.1.1 through 3.1.5 of this Appendix. Test loads shall consist of energy test cloths, except that adjustments to the test loads to achieve proper weight can be made by the use of energy stuffer cloths with no more than 5 stuffer cloths per load.

2.8 *Use of Test Loads.* Table 2.8 of this Appendix defines the test load sizes and corresponding water fill settings which are to be used when measuring water and energy consumptions. Adaptive water fill control system and manual water fill control system are defined in section 1 of this Appendix:

TABLE 2.8—TEST LOAD SIZES AND WATER FILL SETTINGS REQUIRED

Manual water fill control system		Adaptive water fill control system	
Test load size	Water fill setting	Test load size	Water fill setting
Max	Max	Max	As determined by the Clothes Washer.
Min	Min	Avg Min.	

2.8.1 The test load sizes to be used to measure RMC are specified in section 3.8.1 of this Appendix.

2.8.2 Test loads for energy and water consumption measurements shall be bone dry prior to the first cycle of the test, and dried to a maximum of 104 percent of bone dry weight for subsequent testing.

2.8.3 Load the energy test cloths by grasping them in the center, shaking them to hang loosely and then put them into the clothes container prior to activating the clothes washer.

2.9 *Pre-conditioning of Clothes Washer.*

2.9.1 *Non-water-heating clothes washer.* If the clothes washer has not been filled with water in the preceding 96 hours, pre-condition it by running it through a cold rinse cycle and then draining it to ensure that the hose, pump, and sump are filled with water.

2.9.2 *Water-heating clothes washer.* If the clothes washer has not been filled with water in the preceding 96 hours, or if it has not been in the test room at the specified ambient conditions for 8 hours, pre-condition it by running it through a cold rinse cycle and then draining it to ensure that the hose, pump, and sump are filled with water.

2.10 *Wash time setting.* If one wash time is prescribed in the energy test cycle, that shall be the wash time setting; otherwise, the wash time setting shall be the higher of either the minimum or 70 percent of the maximum wash time available in the energy test cycle, regardless of the labeling of suggested dial locations. If the clothes washer is equipped with an electromechanical dial controlling wash time, reset the dial to the minimum wash time and then turn it in the direction of increasing wash time to reach the appropriate setting. If the appropriate setting is passed, return the dial to the minimum wash time and then turn in the direction of increasing wash time until the setting is reached.

2.11 *Test room temperature.* For all clothes washers, maintain the test room ambient air temperature at 75 ± 5 °F (23.9 ± 2.8 °C) for active mode testing and combined low-power mode testing. Do not use the test room ambient air temperature conditions specified in Section 4, Paragraph 4.2 of IEC 62301 for combined low-power mode testing.

2.12 *Bone dryer temperature.* The dryer used for bone drying must heat the test cloth and energy stuffer cloths above 210 °F (99 °C).

2.13 *Energy consumption for the purpose of certifying the cycle selection(s) to be included in Part (B) of the energy test cycle definition.* Where multiple alternate cycle selections offer a wash/rinse temperature selection for which a TUF has been developed, and that is not available on the cycle selection recommended by the manufacturer for washing cotton or linen clothes described in Part (A) of the energy test cycle definition, the alternate cycle selection with the highest energy consumption for that TUF, as measured according to this section, shall be included in the energy test cycle.

2.13.1 For the TUF being considered under this section, establish the testing conditions set forth in section 2 of this test procedure. Select the applicable cycle selection and temperature selection. Use the manufacturer default settings for agitation/tumble operation, soil level, spin speed(s), wash times, rinse times, and all other wash parameters or optional features applicable to that cycle selection, including water heating time for water heating clothes washers.

2.13.2 Use the clothes washer's maximum test load size, determined from Table 5.1, for testing under this section.

2.13.3 For clothes washers with a manual water fill control system, user-adjustable adaptive water fill control system, or adaptive water fill control system with alternate manual water fill control system, use the water fill selector setting resulting in the maximum water level available for each cycle selection for testing under this section.

2.13.4 Each wash cycle tested under this section shall include the entire active washing mode and exclude any delay start or cycle finished modes.

2.13.5 Measure each cycle selection's electrical energy consumption (E_B) and hot water consumption (H_B). Calculate the total energy consumption for each cycle selection (E_{TB}), as follows:

$E_{TB} = E_B + (H_B \times T \times K)$

Where:

E_B is the electrical energy consumption, expressed in kilowatt-hours per cycle.

H_B is the hot water consumption, expressed in gallons per cycle.

T = temperature rise = 75 °F (41.7 °C)

K = Water specific heat in kilowatt-hours per gallon per degree F = 0.00240 kWh/gal-°F (0.00114 kWh/L-°C)

3. Test Measurements

3.1 *Clothes container capacity.* Measure the entire volume which a clothes load could occupy within the clothes container during active mode washer operation according to the following procedures:

3.1.1 Place the clothes washer in such a position that the uppermost edge of the clothes container opening is leveled horizontally, so that the container will hold the maximum amount of water. For front-loading clothes washers, the shipping bolts and door seal shall remain in place during the capacity measurement.

3.1.2 Line the inside of the clothes container with 2 mil (0.051 mm) plastic sheet. All clothes washer components which occupy space within the clothes container and which are recommended for use with the energy test cycle shall be in place and shall be lined with 2 mil (0.051 mm) plastic sheet to prevent water from entering any void space.

3.1.3 Record the total weight of the machine before adding water.

3.1.4 Fill the clothes container manually with either 60 °F ± 5 °F (15.6 °C ± 2.8 °C) or 100 °F ± 10 °F (37.8 °C ± 5.5 °C) water, with the door open. For a top-loading, vertical-axis clothes washer, fill the clothes container to the uppermost edge of the rotating portion, including any balance ring. For a front-loading, horizontal-axis clothes washer, fill the clothes container to the uppermost edge that is in contact with the door seal. For all clothes washers, any volume which cannot be occupied by the clothing load during operation must be excluded from the measurement. Measure and record the weight of water, W, in pounds.

3.1.5 The clothes container capacity is calculated as follows:

$C = W/d$

Where:

C = Capacity in cubic feet (liters).

W = Mass of water in pounds (kilograms).

d = Density of water (62.0 lbs/ft^3 for 100 °F (993 kg/m^3 for 37.8 °C) or 62.3 lbs/ft^3 for 60 °F (998 kg/m^3 for 15.6 °C)).

3.2 *Procedure for measuring water and energy consumption values on all automatic and semi-automatic washers.* All energy consumption tests shall be performed under the energy test cycle(s), unless otherwise specified. Table 3.2 of this Appendix defines the sections below which govern tests of particular clothes washers, based on the number of wash/rinse temperature selections available on the model, and also, in some instances, method of water heating. The procedures prescribed are applicable regardless of a clothes washer's washing capacity, loading port location, primary axis of rotation of the clothes container, and type of control system.

3.2.1 *Inlet water temperature and the wash/rinse temperature settings.*

3.2.1.1 For automatic clothes washers, set the wash/rinse temperature selection control to obtain the wash water temperature selection desired (extra hot, hot, warm, or cold) and cold rinse, and open both the hot and cold water faucets.

3.2.1.2 For semi-automatic washers:

(1) For hot water temperature, open the hot water faucet completely and close the cold water faucet;

(2) For warm inlet water temperature, open both hot and cold water faucets completely;

(3) For cold water temperature, close the hot water faucet and open the cold water faucet completely.

3.2.1.3 *Determination of warm wash water temperature(s) to decide whether a clothes washer has uniformly distributed warm wash temperature selections.* The wash water temperature, Tw, of each warm water wash selection shall be calculated or measured.

(1) For non-water heating clothes washers, calculate Tw as follows:

$Tw(°F) = ((Hw \times 135\ °F) + (Cw \times 60\ °F))/(Hw + Cw)$

or

$Tw(°C) = ((Hw \times 57.2\ °C) + (Cw \times 15.6\ °C))/(Hw + Cw)$

Where:

Hw = Hot water consumption of a warm wash.

Cw = Cold water consumption of a warm wash.

(2) For water-heating clothes washers, measure and record the temperature of each warm wash selection after fill.

3.2.2 Total water consumption during the energy test cycle shall be measured, including hot and cold water consumption during wash, deep rinse, and spray rinse.

3.2.3 *Clothes washers with adaptive water fill/manual water fill control systems.*

3.2.3.1 *Clothes washers with adaptive water fill control system and alternate manual water fill control systems.* If a clothes washer with an adaptive water fill control system allows consumer selection of manual controls as an alternative, then both manual and adaptive modes shall be tested and, for each mode, the energy consumption (HE_T, ME_T, and D_E) and water consumption (Q_T), values shall be calculated as set forth in section 4 of this Appendix. Then the average of the two values (one from each mode, adaptive and manual) for each variable shall be used in section 4 of this Appendix for the clothes washer.

3.2.3.2 *Clothes washers with adaptive water fill control system.*

3.2.3.2.1 Not user adjustable. The maximum, minimum, and average water levels as defined in the following sections shall be interpreted to mean that amount of water fill which is selected by the control system when the respective test loads are used, as defined in Table 2.8 of this Appendix. The load usage factors which shall be used when calculating energy consumption values are defined in Table 4.1.3 of this Appendix.

3.2.3.2.2 User adjustable. Four tests shall be conducted on clothes washers with user adjustable adaptive water fill controls which affect the relative wash water levels. The first test shall be conducted with the maximum test load and with the adaptive water fill control system set in the setting that will give the most energy intensive result. The second test shall be conducted with the minimum test load and with the adaptive water fill control system set in the setting that will give the least energy intensive result. The third test shall be conducted with the average test load and with the adaptive water fill control system set in the setting that will give the most energy intensive result for the given test load. The fourth test shall be conducted with the average test load and with the adaptive water fill control system set in the setting that will give the least energy intensive result for the given test load. The energy and water consumption for the average test load and water level shall be the average of the third and fourth tests.

3.2.3.3 *Clothes washers with manual water fill control system.* In accordance with Table 2.8 of this Appendix, the water fill selector shall be set to the maximum water level available on the clothes washer for the maximum test load size and set to the minimum water level for the minimum test load size. The load usage factors which shall be used when calculating energy consumption values are defined in Table 4.1.3 of this Appendix.

TABLE 3.2—TEST SECTION REFERENCE

Max. wash temp. available	≤135 °F (57.2 °C)			>135 °F (57.2 °C)**	
Number of wash temp. selections	1	2	>2	3	>3
Test sections required to be followed	.....	.....	.....	3.3	3.3
	.....	3.4	3.4	.....	3.4
	.....	.....	3.5	3.5	3.5
	3.6	3.6	3.6	3.6	3.6

TABLE 3.2—TEST SECTION REFERENCE—Continued

Max. wash temp. available	≤135 °F (57.2 °C)			>135 °F (57.2 °C)**	
Number of wash temp. selections	1	2	>2	3	>3
	..... 3.8	..... 3.8	*3.7 3.8	*3.7 3.8	*3.7 3.8

*Only applicable to machines with warm rinse.
**Only applicable to water heating clothes washers on which the maximum wash temperature available exceeds 135 °F (57.2 °C).

3.3 *''Extra Hot Wash'' (Max Wash Temp >135 °F (57.2 °C)) for water heating clothes washers only.* Water and electrical energy consumption shall be measured for each water fill level and/or test load size as specified in sections 3.3.1 through 3.3.3 of this Appendix for the hottest wash setting available.

3.3.1 *Maximum test load and water fill.* Hot water consumption (Hm_x), cold water consumption (Cm_x), and electrical energy consumption (Em_x) shall be measured for an extra hot wash/cold rinse energy test cycle, with the controls set for the maximum water fill level. The maximum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.3.2 *Minimum test load and water fill.* Hot water consumption (Hm_n), cold water consumption (Cm_n), and electrical energy consumption (Em_n) shall be measured for an extra hot wash/cold rinse energy test cycle, with the controls set for the minimum water fill level. The minimum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.3.3 *Average test load and water fill.* For clothes washers with an adaptive water fill control system, measure the values for hot water consumption (Hm_a), cold water consumption (Cm_a), and electrical energy consumption (Em_a) for an extra hot wash/cold rinse energy test cycle, with an average test load size as determined per Table 5.1 of this Appendix.

3.4 *''Hot Wash'' (Max Wash Temp ≤135 °F (57.2 °C)).* Water and electrical energy consumption shall be measured for each water fill level and/or test load size as specified in sections 3.4.1 through 3.4.3 of this Appendix for a 135 °F (57.2 °C) wash, if available, or for the hottest selection less than 135 °F (57.2 °C).

3.4.1 *Maximum test load and water fill.* Hot water consumption (Hh_x), cold water consumption (Ch_x), and electrical energy consumption (Eh_x) shall be measured for a hot wash/cold rinse energy test cycle, with the controls set for the maximum water fill level. The maximum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.4.2 *Minimum test load and water fill.* Hot water consumption (Hh_n), cold water consumption (Ch_n), and electrical energy consumption (Eh_n) shall be measured for a hot wash/cold rinse energy test cycle, with the controls set for the minimum water fill level. The minimum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.4.3 *Average test load and water fill.* For clothes washers with an adaptive water fill control system, measure the values for hot water consumption (Hh_a), cold water consumption (Ch_a), and electrical energy consumption (Eh_a) for a hot wash/cold rinse energy test cycle, with an average test load size as determined per Table 5.1 of this Appendix.

3.5 *''Warm Wash.''* Water and electrical energy consumption shall be determined for each water fill level and/or test load size as specified in sections 3.5.1 through 3.5.2.3 of this Appendix for the applicable warm water wash temperature(s) with a cold rinse.

3.5.1 *Clothes washers with uniformly distributed warm wash temperature selection(s).* The reportable values to be used for the warm water wash setting shall be the arithmetic average of the measurements for the hot and cold wash selections. This is a calculation only; no testing is required.

3.5.2 *Clothes washers that lack uniformly distributed warm wash temperature selections.* For a clothes washer with fewer than four discrete warm wash selections, test all warm wash temperature selections. For a clothes washer that offers four or more warm wash selections, test at all discrete selections, or test at 25 percent, 50 percent, and 75 percent positions of the temperature selection device between the hottest hot (≤135 °F (57.2 °C)) wash and the coldest cold wash. If a selection is not available at the 25, 50 or 75 percent position, in place of each such unavailable selection use the next warmer setting. Each reportable value to be used for the warm water wash setting shall be the arithmetic average of all tests conducted pursuant to this section.

3.5.2.1 *Maximum test load and water fill.* Hot water consumption (Hw_x), cold water consumption (Cw_x), and electrical energy consumption (Ew_x) shall be measured with the controls set for the maximum water fill level. The maximum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.5.2.2 *Minimum test load and water fill.* Hot water consumption (Hw_n), cold water consumption (Cw_n), and electrical energy consumption (Ew_n) shall be measured with the controls set for the minimum water fill level. The minimum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.5.2.3 *Average test load and water fill.* For clothes washers with an adaptive water fill control system, measure the values for hot water consumption (Hw_a), cold water consumption (Cw_a), and electrical energy consumption (Ew_a) with an average test load size as determined per Table 5.1 of this Appendix.

3.6 *''Cold Wash'' (Minimum Wash Temperature Selection).* Water and electrical energy consumption shall be measured for each water fill level and/or test load size as specified in sections 3.6.1 through 3.6.3 of this Appendix for the coldest wash temperature selection available. For a clothes washer that offers two or more wash temperature settings labeled as cold, such as ''Cold'' and ''Tap Cold'', the setting with the minimum wash temperature shall be considered the cold wash. If any of the other cold wash temperature settings add hot water to raise the wash temperature above the cold water supply temperature, as defined in section 2.3 of this Appendix, those setting(s) shall be considered warm wash setting(s), as defined in section 1.34 of this Appendix. If none of the cold wash temperature settings add hot water for any of the water fill levels or test load sizes required for the energy test cycle, the wash temperature setting labeled as ''Cold'' shall be considered the cold wash, and the other wash temperature setting(s) labeled as cold shall not be required for testing.

3.6.1 *Maximum test load and water fill.* Hot water consumption (Hc_x), cold water consumption (Cc_x), and electrical energy consumption (Ec_x) shall be measured for a cold wash/cold rinse energy test cycle, with the controls set for the maximum water fill level. The maximum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.6.2 *Minimum test load and water fill.* Hot water consumption (Hc_n), cold water consumption (Cc_n), and electrical energy consumption (Ec_n) shall be measured for a cold wash/cold rinse energy test cycle, with the controls set for the minimum water fill level. The minimum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.6.3 *Average test load and water fill.* For clothes washers with an adaptive water fill control system, measure the values for hot water consumption (Hc_a), cold water consumption (Cc_a), and electrical energy consumption (Ec_a) for a cold wash/cold rinse energy test cycle, with an average test load size as determined per Table 5.1 of this Appendix.

3.7 *''Warm Wash/Warm Rinse.''* Water and electrical energy consumption shall be determined for each water fill level and/or test load size as specified in sections 3.7.2.1 through 3.7.2.3 of this Appendix for the applicable warm wash temperature selection as described in section 3.7.1 or 3.7.2 of this Appendix and the hottest available rinse temperature selection.

3.7.1 *Clothes washers with uniformly distributed warm wash temperature selection(s).* Test the warm wash/warm rinse cycle at the wash temperature selection with the temperature selection device at the 50

percent position between the hottest hot (≤135 °F (57.2 °C)) wash and the coldest cold wash.

3.7.2 *Clothes washers that lack uniformly distributed warm wash temperature selections.* For a clothes washer with fewer than four discrete warm wash selections, test all warm wash temperature selections for which a warm rinse is available. For a clothes washer that offers four or more warm wash selections, test at all discrete selections for which a warm rinse is available, or test at 25 percent, 50 percent, and 75 percent positions of the temperature selection device between the hottest hot (≤135 °F (57.2 °C)) wash and the coldest cold wash. If a selection is not available at the 25, 50, or 75 percent position, in place of each such unavailable selection use the next warmer setting. Each reportable value to be used for the warm wash/warm rinse setting shall be the arithmetic average of all tests conducted pursuant to this section.

3.7.2.1 *Maximum test load and water fill.* Hot water consumption (Hww_x), cold water consumption (Cww_x), and electrical energy consumption (Eww_x) shall be measured with the controls set for the maximum water fill level. The maximum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.7.2.2 *Minimum test load and water fill.* Hot water consumption (Hww_n), cold water consumption (Cww_n), and electrical energy consumption (Eww_n) shall be measured with the controls set for the minimum water fill level. The minimum test load size is to be used and shall be determined per Table 5.1 of this Appendix.

3.7.2.3 *Average test load and water fill.* For clothes washers with an adaptive water fill control system, measure the values for hot water consumption (Hww_a), cold water consumption (Cww_a), and electrical energy consumption (Eww_a) with an average test load size as determined per Table 5.1 of this Appendix.

3.8 *Remaining Moisture Content:*

3.8.1 The wash temperature will be the same as the rinse temperature for all testing. Use the maximum test load as defined in Table 5.1 of this Appendix for testing.

3.8.2 *For clothes washers with cold rinse only:*

3.8.2.1 Record the actual ''bone dry'' weight of the test load (WI_x), then place the test load in the clothes washer.

3.8.2.2 Set water level selector to maximum fill.

3.8.2.3 Run the energy test cycle.

3.8.2.4 Record the weight of the test load immediately after completion of the energy test cycle (WC_x).

3.8.2.5 Calculate the remaining moisture content of the maximum test load, RMC_x, defined as:

$$RMC_x = (WC_x - WI_x)/WI_x$$

3.8.2.6 Apply the RMC correction curve described in section 2.6.7 of this Appendix to calculate the corrected remaining moisture content, RMC_{corr}, expressed as a percentage, which shall be the final RMC used in section 4.3 of this Appendix:

$$RMC_{corr} = (A \times RMC_x + B) \times 100\%$$

Where:

A and B are the coefficients of the RMC correction curve as defined in section 2.6.6.1 of this Appendix.

RMC_x = As defined in section 3.8.2.5 of this Appendix.

3.8.3 *For clothes washers with cold and warm rinse options:*

3.8.3.1 Complete sections 3.8.2.1 through 3.8.2.4 of this Appendix for cold rinse.

Calculate the remaining moisture content of the maximum test load for cold rinse, RMC_{COLD}, defined as:

$$RMC_{COLD} = (WC_x - WI_x)/WI_x$$

3.8.3.2 Apply the RMC correction curve described in section 2.6.7 of this Appendix to calculate the corrected remaining moisture content for cold rinse, $RMC_{COLD,corr}$, expressed as a percentage, as follows:

$$RMC_{COLD,corr} = (A \times RMC_{COLD} + B) \times 100\%$$

Where:

A and B are the coefficients of the RMC correction curve as defined in section 2.6.6.1 of this Appendix.

RMC_{COLD} = As defined in section 3.8.3.1 of this Appendix.

3.8.3.3 Complete sections 3.8.2.1 through 3.8.2.4 of this Appendix for warm rinse. Calculate the remaining moisture content of the maximum test load for warm rinse, RMC_{WARM}, defined as:

$$RMC_{WARM} = (WC_x - WI_x)/WI_x$$

3.8.3.4 Apply the RMC correction curve described in section 2.6.7 of this Appendix to calculate the corrected remaining moisture content for warm rinse, $RMC_{WARM,corr}$, expressed as a percentage, as follows:

$$RMC_{WARM,corr} = (A \times RMC_{WARM} + B) \times 100\%$$

Where:

A and B are the coefficients of the RMC correction curve as defined in section 2.6.6.1 of this Appendix.

RMC_{WARM} = As defined in section 3.8.3.3 of this Appendix.

3.8.3.5 Calculate the corrected remaining moisture content of the maximum test load, RMC_{corr}, expressed as a percentage, which shall be the final RMC used in section 4.3 of this Appendix:

$$RMC_{corr} = RMC_{COLD,corr} \times (1 - TUF_{ww}) + RMC_{WARM,corr} \times (TUF_{ww})$$

Where:

$RMC_{COLD,corr}$ = As defined in section 3.8.3.2 of this Appendix.

$RMC_{WARM,corr}$ = As defined in section 3.8.3.4 of this Appendix.

TUF_{ww} is the temperature use factor for warm rinse as defined in Table 4.1.1 of this Appendix.

3.8.4 Clothes washers that have options such as multiple selections of spin speeds or spin times that result in different RMC values and that are available in the energy test cycle, shall be tested at the maximum and minimum extremes of the available options, excluding any ''no spin'' (zero spin speed) settings, in accordance with requirements in section 3.8.2 or 3.8.3 of this Appendix, as applicable. The calculated $RMC_{corr,max\ extraction}$ and $RMC_{corr,min\ extraction}$ at the maximum and minimum settings, respectively, shall be combined as follows and the final corrected RMC to be used in section 4.3 of this Appendix shall be:

$$RMC_{corr} = 0.75 \times RMC_{corr,max\ extraction} + 0.25 \times RMC_{corr,min\ extraction}$$

Where:

$RMC_{corr,max\ extraction}$ is the corrected remaining moisture content using the maximum spin setting, calculated according to section 3.8.2 or 3.8.3 of this Appendix, as applicable.

$RMC_{corr,min\ extraction}$ is the corrected remaining moisture content using the minimum spin setting, calculated according to section 3.8.2 or 3.8.3 of this Appendix, as applicable.

3.9 *Combined low-power mode power.* Connect the clothes washer to a watt meter as specified in section 2.5.3 of this Appendix. Establish the testing conditions set forth in sections 2.1, 2.2 and 2.11 of this Appendix. For clothes washers that take some time to enter a stable state from a higher power state as discussed in Section 5, Paragraph 5.1, note 1 of IEC 62301 (incorporated by reference; see § 430.3), allow sufficient time for the clothes washer to reach the lower power state before proceeding with the test measurement. Follow the test procedure for the sampling method specified in Section 5, Paragraph 5.3.2 of IEC 62301 for testing in each possible mode as described in sections 3.9.1 and 3.9.2 of this Appendix.

3.9.1 If a clothes washer has an inactive mode as defined in section 1.15 of this Appendix, measure and record the average inactive mode power of the clothes washer, P_{ia}, in watts.

3.9.2 If a clothes washer has an off mode as defined in section 1.24 of this Appendix, measure and record its average off mode power, P_o, in watts.

4. Calculation of Derived Results From Test Measurements

4.1 *Hot water and machine electrical energy consumption of clothes washers.*

4.1.1 *Per-cycle temperature-weighted hot water consumption for maximum, average, and minimum water fill levels using each appropriate load size as defined in section 2.8 and Table 5.1 of this Appendix.* Calculate for the cycle under test the per-cycle temperature-weighted hot water consumption for the maximum water fill level, Vh_x, the average water fill level, Vh_a, and the minimum water fill level, Vh_n, expressed in gallons per cycle (or liters per cycle) and defined as:

(a) $Vh_x = [Hm_x \times TUF_m] + [Hh_x \times TUF_h] + [Hw_x \times TUF_w] + [Hww_x \times TUF_{ww}] + [Hc_x \times TUF_c]$

(b) $Vh_a = [Hm_a \times TUF_m] + [Hh_a \times TUF_h] + [Hw_a \times TUF_w] + [Hww_a \times TUF_{ww}] + [Hc_a \times TUF_c]$

(c) $Vh_n = [Hm_n \times TUF_m] + [Hh_n \times TUF_h] + [Hw_n \times TUF_w] + [Hww_n \times TUF_{ww}] + [Hc_n \times TUF_c]$

Where:

Hm_x, Hm_a, and Hm_n, are reported hot water consumption values, in gallons per-cycle (or liters per cycle), at maximum, average, and minimum water fill, respectively, for the extra hot wash cycle with the appropriate test loads as defined in section 2.8 of this Appendix.

Hh_x, Hh_a, and Hh_n, are reported hot water consumption values, in gallons per-cycle

(or liters per cycle), at maximum, average, and minimum water fill, respectively, for the hot wash cycle with the appropriate test loads as defined in section 2.8 of this Appendix.

Hw_x, Hw_a, and Hw_n, are reported hot water consumption values, in gallons per-cycle (or liters per cycle), at maximum, average, and minimum water fill, respectively, for the warm wash cycle with the appropriate test loads as defined in section 2.8 of this Appendix.

Hww_x, Hww_a, and Hww_n, are reported hot water consumption values, in gallons per-cycle (or liters per cycle), at maximum, average, and minimum water fill, respectively, for the warm wash/warm rinse cycle with the appropriate test loads as defined in section 2.8 of this Appendix.

Hc_x, Hc_a, and Hc_n, are reported hot water consumption values, in gallons per-cycle (or liters per cycle), at maximum, average, and minimum water fill, respectively, for the cold wash cycle with the appropriate test loads as defined in section 2.8 of this Appendix.

TUF_m, TUF_h, TUF_w, TUF_{ww}, and TUF_c are temperature use factors for extra hot wash, hot wash, warm wash, warm wash/warm rinse, and cold wash temperature selections, respectively, and are as defined in Table 4.1.1 of this Appendix.

TABLE 4.1.1—TEMPERATURE USE FACTORS

Max wash temp available	≤135 °F (57.2 °C)			>135 °F (57.2 °C)	
No. wash temp selections	Single	2 Temps	>2 Temps	3 Temps	>3 Temps
TUF_m (extra hot)	.....	.....	.....	0.14	0.05
TUF_h (hot)	.....	0.63	0.14	.....	0.09
TUF_{ww} (warm/warm)	.....	.....	* 0.27	* 0.27	* 0.27
TUF_w (warm)	.....	.....	** 0.22/0.49	** 0.22/0.49	** 0.22/0.49
TUF_c (cold)	1.00	0.37	0.37	0.37	0.37

* Only applicable to machines offering a warm/warm cycle. For machines with no warm/warm cycle, TUF_{ww} (warm/warm) should be zero.
** For machines offering a warm/warm cycle, TUF_w (warm) should be 0.22. For machines with no warm/warm cycle, TUF_w (warm) should be 0.49.

4.1.2 *Total per-cycle hot water energy consumption for all maximum, average, and minimum water fill levels tested.* Calculate the total per-cycle hot water energy consumption for the maximum water fill level, HE_{max}, the minimum water fill level, HE_{min}, and the average water fill level, HE_{avg}, expressed in kilowatt-hours per cycle and defined as:

(a) $HE_{max} = [Vh_x \times T \times K]$=Total energy when a maximum load is tested.

(b) $HE_{avg} = [Vh_a \times T \times K]$=Total energy when an average load is tested.

(c) $HE_{min} = [Vh_n \times T \times K]$=Total energy when a minimum load is tested.

Where:

Vh_x, Vh_a, and Vh_n are as defined in section 4.1.1 of this Appendix.

T = Temperature rise = 75 °F (41.7 °C).

K = Water specific heat in kilowatt-hours per gallon per degree F = 0.00240 kWh/gal-°F (0.00114 kWh/L-°C).

4.1.3 *Total weighted per-cycle hot water energy consumption.* Calculate the total weighted per-cycle hot water energy consumption, HE_T, expressed in kilowatt-hours per cycle and defined as:

$HE_T = [HE_{max} \times F_{max}] + [HE_{avg} \times F_{avg}] + HE_{min} \times F_{min}]$

Where:

HE_{max}, HE_{avg}, and HE_{min} are as defined in section 4.1.2 of this Appendix.

F_{max}, F_{avg}, and F_{min} are the load usage factors for the maximum, average, and minimum test loads based on the size and type of the control system on the washer being tested. The values are as shown in Table 4.1.3 of this Appendix.

TABLE 4.1.3—LOAD USAGE FACTORS

Water fill control system	Manual	Adaptive
F_{max} = ...	[1] 0.72	[2] 0.12
F_{avg} = ...	.....	[2] 0.74
F_{min} = ...	[1] 0.28	[2] 0.14

[1] Reference 3.2.3.3.
[2] Reference 3.2.3.2.

4.1.4 *Total per-cycle hot water energy consumption using gas-heated or oil-heated water.* Calculate for the energy test cycle the per-cycle hot water consumption, HE_{TG}, using gas-heated or oil-heated water, expressed in Btu per cycle (or megajoules per cycle) and defined as:

$HE_{TG} = HE_T \times 1/e \times 3412$ Btu/kWh or $HE_{TG} = HE_T \times 1/e \times 3.6$ MJ/kWh

Where:

e = Nominal gas or oil water heater efficiency = 0.75.

HE_T = As defined in section 4.1.3 of this Appendix.

4.1.5 *Per-cycle machine electrical energy consumption for all maximum, average, and minimum test load sizes.* Calculate the total per-cycle machine electrical energy consumption for the maximum water fill level, ME_{max}, the average water fill level, ME_{avg}, and the minimum water fill level, ME_{min}, expressed in kilowatt-hours per cycle and defined as:

(a) $ME_{max} = [Em_x \times TUF_m] + [Eh_x \times TUF_h] + + [Ew_x \times TUF_w] + + [Eww_x \times TUF_{ww}] + [Ec_x \times TUF_c]$

(b) $ME_{avg} = [Em_a \times TUF_m] + [Eh_a \times TUF_h] + [Ew_a \times TUF_w] + + [Eww_a \times TUF_{ww}] + + [Ec_a \times TUF_c]$

(c) $ME_{min} = [Em_n \times TUF_m] + + [Eh_n \times TUF_h] + + [Ew_n \times TUF_w] + + [Eww_n \times TUF_{ww}] + [Ec_n \times TUF_c]$

Where:

Em_x, Em_a, and Em_n, are reported electrical energy consumption values, in kilowatt-hours per cycle, at maximum, average, and minimum test loads, respectively, for the extra hot wash cycle.

Eh_x, Eh_a, and Eh_n, are reported electrical energy consumption values, in kilowatt-hours per cycle, at maximum, average, and minimum test loads, respectively, for the hot wash cycle.

Ew_x, Ew_a, and Ew_n, are reported electrical energy consumption values, in kilowatt-hours per cycle, at maximum, average, and minimum test loads, respectively, for the warm wash cycle.

Eww_x, Eww_a, and Eww_n, are reported electrical energy consumption values, in kilowatt-hours per cycle, at maximum, average, and minimum test loads, respectively, for the warm wash/warm rinse cycle.

Ec_x, Ec_a, and Ec_n, are reported electrical energy consumption values, in kilowatt-hours per cycle, at maximum, average, and minimum test loads, respectively, for the cold wash cycle.

TUF_m, TUF_h, TUF_w, TUF_{ww}, and TUF_c are as defined in Table 4.1.1 of this Appendix.

4.1.6 *Total weighted per-cycle machine electrical energy consumption.* Calculate the total weighted per-cycle machine electrical energy consumption, ME_T, expressed in kilowatt-hours per cycle and defined as:

$ME_T = [ME_{max} \times F_{max}] + + [ME_{avg} \times F_{avg}] + + [ME_{min} \times F_{min}]$

Where:

ME_{max}, ME_{avg}, and ME_{min} are as defined in section 4.1.5 of this Appendix.

F_{max}, F_{avg}, and F_{min} are as defined in Table 4.1.3 of this Appendix.

4.1.7 *Total per-cycle energy consumption when electrically heated water is used.* Calculate for the energy test cycle the total per-cycle energy consumption, E_{TE}, using electrically heated water, expressed in kilowatt-hours per cycle and defined as:

$E_{TE} = HE_T + ME_T$

Where:

ME_T = As defined in section 4.1.6 of this Appendix.

HE_T = As defined in section 4.1.3 of this Appendix.

4.2 *Water consumption of clothes washers.*

4.2.1 *Per-cycle water consumption for extra hot wash.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the extra hot wash cycle and defined as:

$Qm_{max} = [Hm_x + Cm_x]$
$Qm_{avg} = [Hm_a + Cm_a]$
$Qm_{min} = [Hm_n + Cm_n]$

Where:

Hm_x, Cm_x, Hm_a, Cm_a, Hm_n, and Cm_n are defined in section 3.3 of this Appendix.

4.2.2 *Per-cycle water consumption for hot wash.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the hot wash cycle and defined as:

$Qh_{max} = [Hh_x + Ch_x]$
$Qh_{avg} = [Hh_a + Ch_a]$
$Qh_{min} = [Hh_n + Ch_n]$

Where:

Hh_x, Ch_x, Hh_a, Ch_a, Hh_n, and Ch_n are defined in section 3.4 of this Appendix.

4.2.3 *Per-cycle water consumption for warm wash with cold rinse.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the warm wash/cold rinse cycle and defined as:

$Qw_{max} = [Hw_x + Cw_x]$
$Qw_{avg} = [Hw_a + Cw_a]$
$Qw_{min} = [Hw_n + Cw_n]$

Where:

Hw_x, Cw_x, Hw_a, Cw_a, Hw_n, and Cw_n are defined in section 3.5 of this Appendix.

4.2.4 *Per-cycle water consumption for warm wash with warm rinse.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the warm wash/warm rinse cycle and defined as:

$Qww_{max} = [Hww_x + Cww_x]$
$Qww_{avg} = [Hww_a + Cww_a]$
$Qww_{min} = [Hww_n + Cww_n]$

Where:

Hww_x, Cww_x, Hww_a, Cww_a, Hww_n, and Cww_n are defined in section 3.7 of this Appendix.

4.2.5 *Per-cycle water consumption for cold wash.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the cold wash cycle and defined as:

$Qc_{max} = [Hc_x + Cc_x]$
$Qc_{avg} = [Hc_a + Cc_a]$
$Qc_{min} = [Hc_n + Cc_n]$

Where:

Hc_x, Cc_x, Hc_a, Cc_a, Hc_n, and Cc_n are defined in section 3.6 of this Appendix.

4.2.6 *Total weighted per-cycle water consumption for extra hot wash.* Calculate the total weighted per-cycle water consumption for the extra hot wash cycle, Qm_T, expressed in gallons per cycle (or liters per cycle) and defined as:

$Qm_T = [Qm_{max} \times F_{max}] + [Qm_{avg} \times F_{avg}] + [Qm_{min} \times F_{min}]$

Where:

Qm_{max}, Qm_{avg}, Qm_{min} are defined in section 4.2.1 of this Appendix.

F_{max}, F_{avg}, F_{min} are defined in Table 4.1.3 of this Appendix.

4.2.7 *Total weighted per-cycle water consumption for hot wash.* Calculate the total weighted per-cycle water consumption for the hot wash cycle, Qh_T, expressed in gallons per cycle (or liters per cycle) and defined as:

$Qh_T = [Qh_{max} \times F_{max}] + [Qh_{avg} \times F_{avg}] + [Qh_{min} \times F_{min}]$

Where:

Qh_{max}, Qh_{avg}, Qh_{min} are defined in section 4.2.2 of this Appendix.

F_{max}, F_{avg}, F_{min} are defined in Table 4.1.3 of this Appendix.

4.2.8 *Total weighted per-cycle water consumption for warm wash with cold rinse.* Calculate the total weighted per-cycle water consumption for the warm wash/cold rinse cycle, Qw_T, expressed in gallons per cycle (or liters per cycle) and defined as:

$Qw_T = [Qw_{max} \times F_{max}] + [Qw_{avg} \times F_{avg}] + [Qw_{min} \times F_{min}]$

Where:

Qw_{max}, Qw_{avg}, Qw_{min} are defined in section 4.2.3 of this Appendix.

F_{max}, F_{avg}, F_{min} are defined in Table 4.1.3 of this Appendix.

4.2.9 *Total weighted per-cycle water consumption for warm wash with warm rinse.* Calculate the total weighted per-cycle water consumption for the warm wash/warm rinse cycle, Qww_T, expressed in gallons per cycle (or liters per cycle) and defined as:

$Qww_T = [Qww_{max} \times F_{max}] + [Qww_{avg} \times F_{avg}] + [Qww_{min} \times F_{min}]$

Where:

Qww_{max}, Qww_{avg}, Qww_{min} are defined in section 4.2.4 of this Appendix.

F_{max}, F_{avg}, F_{min} are defined in Table 4.1.3 of this Appendix.

4.2.10 *Total weighted per-cycle water consumption for cold wash.* Calculate the total weighted per-cycle water consumption for the cold wash cycle, Qc_T, expressed in gallons per cycle (or liters per cycle) and defined as:

$Qc_T = [Qc_{max} \times F_{max}] + [Qc_{avg} \times F_{avg}] + [Qc_{min} \times F_{min}]$

Where:

Qc_{max}, Qc_{avg}, Qc_{min} are defined in section 4.2.5 of this Appendix.

F_{max}, F_{avg}, F_{min} are defined in Table 4.1.3 of this Appendix.

4.2.11 *Total weighted per-cycle water consumption for all wash cycles.* Calculate the total weighted per-cycle water consumption for all wash cycles, Q_T, expressed in gallons per cycle (or liters per cycle) and defined as:

$Q_T = [Qm_T \times TUF_m] + [Qh_T \times TUF_h] + [Qw_T \times TUF_w] + [Qww_T \times TUF_{ww}] + [Qc_T \times TUF_c]$

Where:

Qm_T, Qh_T, Qw_T, Qww_T, and Qc_T are defined in sections 4.2.6 through 4.2.10 of this Appendix.

TUF_m, TUF_h, TUF_w, TUF_{ww}, and TUF_c are defined in Table 4.1.1 of this Appendix.

4.2.12 *Water factor.* Calculate the water factor, WF, expressed in gallons per cycle per cubic foot (or liters per cycle per liter), as:

$WF = Qc_T/C$

Where:

Qc_T = As defined in section 4.2.10 of this Appendix.

C = As defined in section 3.1.5 of this Appendix.

4.2.13 *Integrated water factor.* Calculate the integrated water factor, IWF, expressed in gallons per cycle per cubic foot (or liter per cycle per liter), as:

$IWF = Q_T/C$

Where:

Q_T = As defined in section 4.2.11 of this Appendix.

C = As defined in section 3.1.5 of this Appendix.

4.3 *Per-cycle energy consumption for removal of moisture from test load.* Calculate the per-cycle energy required to remove the remaining moisture of the test load, D_E, expressed in kilowatt-hours per cycle and defined as:

$D_E = [(F_{max} \times \text{Maximum test load weight}) + (F_{avg} \times \text{Average test load weight}) + (F_{min} \times \text{Minimum test load weight})] \times (RMC_{corr} - 4\%) \times (DEF) \times (DUF)$

Where:

F_{max}, F_{avg}, and F_{min} are as defined in Table 4.1.3 of this Appendix.

Maximum, average, and minimum test load weights are as defined in Table 5.1 of this Appendix.

RMC_{corr} = As defined in section 3.8.2.6, 3.8.3.5, or 3.8.4 of this Appendix.

DEF = Nominal energy required for a clothes dryer to remove moisture from clothes = 0.5 kWh/lb (1.1 kWh/kg).

DUF = Dryer usage factor, percentage of washer loads dried in a clothes dryer = 0.91.

4.4 *Per-cycle combined low-power mode energy consumption.* Calculate the per-cycle combined low-power mode energy consumption, E_{TLP}, expressed in kilowatt-hours per cycle and defined as:

$E_{TLP} = [(P_{ia} \times S_{ia}) + (P_o \times S_o)] \times K_p/295.$

Where:

P_{ia} = Washer inactive mode power, in watts, as defined in section 3.9.1 of this Appendix for clothes washers capable of operating in inactive mode; otherwise, $P_{ia} = 0$.

P_o = Washer off mode power, in watts, as defined in section 3.9.2 of this Appendix for clothes washers capable of operating in off mode; otherwise, P_o=0.

S_{ia} = Annual hours in inactive mode as defined as S_{oi} if no off mode is possible, [S_{oi}/2] if both inactive mode and off mode are possible, and 0 if no inactive mode is possible.

S_o = Annual hours in off mode as defined as S_{oi} if no inactive mode is possible, [S_{oi}/2] if both inactive mode and off mode are possible, and 0 if no off mode is possible.

S_{oi} = Combined annual hours for off and inactive mode = 8,465.
K_p = Conversion factor of watt-hours to kilowatt-hours = 0.001.
295 = Representative average number of clothes washer cycles in a year.

4.5 *Modified energy factor.* Calculate the modified energy factor, MEF, expressed in cubic feet per kilowatt-hour per cycle (or liters per kilowatt-hour per cycle) and defined as:

$MEF = C/(E_{TE} + D_E)$

Where:

C = As defined in section 3.1.5 of this Appendix.
E_{TE} = As defined in section 4.1.7 of this Appendix.
D_E = As defined in section 4.3 of this Appendix.

4.6 *Integrated modified energy factor.* Calculate the integrated modified energy factor, IMEF, expressed in cubic feet per kilowatt-hour per cycle (or liters per kilowatt-hour per cycle) and defined as:

$IMEF = C/(E_{TE} + D_E + E_{TLP})$

Where:

C = As defined in section 3.1.5 of this Appendix.
E_{TE} = As defined in section 4.1.7 of this Appendix.
D_E = As defined in section 4.3 of this Appendix.
E_{TLP} = As defined in section 4.4 of this Appendix.

5. Test Loads

TABLE 5.1—TEST LOAD SIZES

Container volume		Minimum load		Maximum load		Average load	
cu. ft. ≥ <	liter ≥ <	lb	kg	lb	kg	lb	kg
0–0.80	0–22.7	3.00	1.36	3.00	1.36	3.00	1.36
0.80–0.90	22.7–25.5	3.00	1.36	3.50	1.59	3.25	1.47
0.90–1.00	25.5–28.3	3.00	1.36	3.90	1.77	3.45	1.56
1.00–1.10	28.3–31.1	3.00	1.36	4.30	1.95	3.65	1.66
1.10–1.20	31.1–34.0	3.00	1.36	4.70	2.13	3.85	1.75
1.20–1.30	34.0–36.8	3.00	1.36	5.10	2.31	4.05	1.84
1.30–1.40	36.8–39.6	3.00	1.36	5.50	2.49	4.25	1.93
1.40–1.50	39.6–42.5	3.00	1.36	5.90	2.68	4.45	2.02
1.50–1.60	42.5–45.3	3.00	1.36	6.40	2.90	4.70	2.13
1.60–1.70	45.3–48.1	3.00	1.36	6.80	3.08	4.90	2.22
1.70–1.80	48.1–51.0	3.00	1.36	7.20	3.27	5.10	2.31
1.80–1.90	51.0–53.8	3.00	1.36	7.60	3.45	5.30	2.40
1.90–2.00	53.8–56.6	3.00	1.36	8.00	3.63	5.50	2.49
2.00–2.10	56.6–59.5	3.00	1.36	8.40	3.81	5.70	2.59
2.10–2.20	59.5–62.3	3.00	1.36	8.80	3.99	5.90	2.68
2.20–2.30	62.3–65.1	3.00	1.36	9.20	4.17	6.10	2.77
2.30–2.40	65.1–68.0	3.00	1.36	9.60	4.35	6.30	2.86
2.40–2.50	68.0–70.8	3.00	1.36	10.00	4.54	6.50	2.95
2.50–2.60	70.8–73.6	3.00	1.36	10.50	4.76	6.75	3.06
2.60–2.70	73.6–76.5	3.00	1.36	10.90	4.94	6.95	3.15
2.70–2.80	76.5–79.3	3.00	1.36	11.30	5.13	7.15	3.24
2.80–2.90	79.3–82.1	3.00	1.36	11.70	5.31	7.35	3.33
2.90–3.00	82.1–85.0	3.00	1.36	12.10	5.49	7.55	3.42
3.00–3.10	85.0–87.8	3.00	1.36	12.50	5.67	7.75	3.52
3.10–3.20	87.8–90.6	3.00	1.36	12.90	5.85	7.95	3.61
3.20–3.30	90.6–93.4	3.00	1.36	13.30	6.03	8.15	3.70
3.30–3.40	93.4–96.3	3.00	1.36	13.70	6.21	8.35	3.79
3.40–3.50	96.3–99.1	3.00	1.36	14.10	6.40	8.55	3.88
3.50–3.60	99.1–101.9	3.00	1.36	14.60	6.62	8.80	3.99
3.60–3.70	101.9–104.8	3.00	1.36	15.00	6.80	9.00	4.08
3.70–3.80	104.8–107.6	3.00	1.36	15.40	6.99	9.20	4.17
3.80–3.90	107.6–110.4	3.00	1.36	15.80	7.16	9.40	4.26
3.90–4.00	110.4–113.3	3.00	1.36	16.20	7.34	9.60	4.35
4.00–4.10	113.3–116.1	3.00	1.36	16.60	7.53	9.80	4.45
4.10–4.20	116.1–118.9	3.00	1.36	17.00	7.72	10.00	4.54
4.20–4.30	118.9–121.8	3.00	1.36	17.40	7.90	10.20	4.63
4.30–4.40	121.8–124.6	3.00	1.36	17.80	8.09	10.40	4.72
4.40–4.50	124.6–127.4	3.00	1.36	18.20	8.27	10.60	4.82
4.50–4.60	127.4–130.3	3.00	1.36	18.70	8.46	10.85	4.91
4.60–4.70	130.3–133.1	3.00	1.36	19.10	8.65	11.05	5.00
4.70–4.80	133.1–135.9	3.00	1.36	19.50	8.83	11.25	5.10
4.80–4.90	135.9–138.8	3.00	1.36	19.90	9.02	11.45	5.19
4.90–5.00	138.8–141.6	3.00	1.36	20.30	9.20	11.65	5.28
5.00–5.10	141.6–144.4	3.00	1.36	20.70	9.39	11.85	5.38
5.10–5.20	144.4–147.2	3.00	1.36	21.10	9.58	12.05	5.47
5.20–5.30	147.2–150.1	3.00	1.36	21.50	9.76	12.25	5.56
5.30–5.40	150.1–152.9	3.00	1.36	21.90	9.95	12.45	5.65
5.40–5.50	152.9–155.7	3.00	1.36	22.30	10.13	12.65	5.75
5.50–5.60	155.7–158.6	3.00	1.36	22.80	10.32	12.90	5.84
5.60–5.70	158.6–161.4	3.00	1.36	23.20	10.51	13.10	5.93
5.70–5.80	161.4–164.2	3.00	1.36	23.60	10.69	13.30	6.03
5.80–5.90	164.2–167.1	3.00	1.36	24.00	10.88	13.50	6.12
5.90–6.00	167.1–169.9	3.00	1.36	24.40	11.06	13.70	6.21

Notes: (1) All test load weights are bone dry weights.
(2) Allowable tolerance on the test load weights are ±0.10 lbs (0.05 kg).

6. Waivers and Field Testing

6.1 *Waivers and Field Testing for Nonconventional Clothes Washers.* Manufacturers of nonconventional clothes washers, such as clothes washers with adaptive control systems, must submit a petition for waiver pursuant to 10 CFR 430.27 to establish an acceptable test procedure for that clothes washer if the washer cannot be tested pursuant to the DOE test procedure or the DOE test procedure yields results that are so unrepresentative of the clothes washer's true energy consumption characteristics as to provide materially inaccurate comparative data. In such cases, field testing may be appropriate for establishing an acceptable test procedure. The following are guidelines for field testing which may be used by manufacturers in support of petitions for waiver. These guidelines are not mandatory and the Department may determine that they do not apply to a particular model. Depending upon a manufacturer's approach for conducting field testing, additional data may be required. Manufacturers are encouraged to communicate with the Department prior to the commencement of field tests which may be used to support a petition for waiver. Section 6.3 of this Appendix provides an example of field testing for a clothes washer with an adaptive water fill control system. Other features, such as the use of various spin speed selections, could be the subject of field tests.

6.2 *Nonconventional Wash System Energy Consumption Test.* The field test may consist of a minimum of 10 of the nonconventional clothes washers (''test clothes washers'') and 10 clothes washers already being distributed in commerce (''base clothes washers''). The tests should include a minimum of 50 energy test cycles per clothes washer. The test clothes washers and base clothes washers should be identical in construction except for the controls or systems being tested. Equal numbers of both the test clothes washer and the base clothes washer should be tested simultaneously in comparable settings to minimize seasonal or consumer laundering conditions or variations. The clothes washers should be monitored in such a way as to accurately record the average total energy and water consumption per cycle, including water heating energy when electrically heated water is used, and the energy required to remove the remaining moisture of the test load. Standby and off mode energy consumption should be measured according to section 4.4 of this test procedure. The field test results should be used to determine the best method to correlate the rating of the test clothes washer to the rating of the base clothes washer.

6.3 *Adaptive water fill control system field test.* (1) Section 3.2.3.1 of this Appendix defines the test method for measuring energy consumption for clothes washers which incorporate both adaptive and alternate manual water fill control systems. Energy consumption calculated by the method defined in section 3.2.3.1 of this Appendix assumes the adaptive cycle will be used 50 percent of the time. This section can be used to develop field test data in support of a petition for waiver when it is believed that the adaptive cycle will be used more than 50 percent of the time. The field test sample size should be a minimum of 10 test clothes washers. The test clothes washers should be representative of the design, construction, and control system that will be placed in commerce. The duration of field testing in the user's house should be a minimum of 50 energy test cycles, for each unit. No special instructions as to cycle selection or product usage should be given to the field test participants, other than inclusion of the product literature pack which would be shipped with all units, and instructions regarding filling out data collection forms, use of data collection equipment, or basic procedural methods. Prior to the test clothes washers being installed in the field test locations, baseline data should be developed for all field test units by conducting laboratory tests as defined by section 1 through section 5 of this Appendix to determine the energy consumption, water consumption, and remaining moisture content values. The following data should be measured and recorded for each wash load during the test period: Wash cycle selected, the mode of the clothes washer (adaptive or manual), clothes load dry weight (measured after the clothes washer and clothes dryer cycles are completed) in pounds, and type of articles in the clothes load (*e.g.,* cottons, linens, permanent press). The wash loads used in calculating the in-home percentage split between adaptive and manual cycle usage should be only those wash loads which conform to the definition of the energy test cycle.

Calculate:

T=The total number of energy test cycles run during the field test.

T_a=The total number of adaptive control energy test cycles.

T_m=The total number of manual control energy test cycles.

The percentage weighting factors:

$P_a=(T_a/T)\times 100\%$ (the percentage weighting for adaptive control selection)

$P_m=(T_m/T)\times 100\%$ (the percentage weighting for manual control selection)

(2) Energy consumption (HE_T, ME_T, and D_E) and water consumption (Q_T), values calculated in section 4 of this Appendix for the manual and adaptive modes, should be combined using P_a and P_m as the weighting factors.

[FR Doc. 2012–4819 Filed 3–6–12; 8:45 a.m.]

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Part V

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1
Federal Acquisition Regulation; Federal Acquisition Circular 2005–57; Introduction; United States-Korea Free Trade Agreement; Small Entity Compliance Guide; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket FAR 2012–0080, Sequence 2]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–57; Introduction

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of an interim rule.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rule agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2005–57. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC. The FAC, including the SECG, is available via the Internet at *http://www.regulations.gov*.

DATES: For effective date and comment date see separate document, which follows.

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below in relation to the FAR case. Please cite FAC 2005–57 and the specific FAR case number. For information pertaining to status or publication schedule, contact the Regulatory Secretariat at 202–501–4755.

LIST OF RULE IN FAC 2005–57

Subject	FAR case	Analyst
United States-Korea Free Trade Agreement (Interim)	2012–004	Erwin

SUPPLEMENTARY INFORMATION: A Summary for the FAR rule follows. For the actual revisions and/or amendments made by this FAR case, refer to FAR Case 2012–004.

FAC 2005–57 amends the FAR as specified below:

United States-Korea Free Trade Agreement (FAR Case 2012–004) (Interim)

This interim rule implements the United States-Korea Free Trade Agreement (see the United States-Korea Free Trade Agreement Implementation Act (Pub. L. 112–41) (19 U.S.C. 3805 note)).

The Republic of Korea is already party to the World Trade Organization Government Procurement Agreement (WTO GPA). This Free Trade Agreement now covers acquisition of supplies and services between $100,000 and the current WTO GPA threshold of $202,000. This interim rule is not expected to have a significant economic impact on a substantial number of small entities.

Dated: March 1, 2012.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Federal Acquisition Circular (FAC) 2005–57 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2005–57 is effective March 15, 2012.

Dated: March 1, 2012.

Richard Ginman,

Director, Defense Procurement and Acquisition Policy.

Dated: March 1, 2012.

Mindy S. Connolly,

Chief Acquisition Officer, U.S. General Services Administration.

Dated: March 1, 2012.

William P. McNally,

Assistant Administrator for Procurement, National Aeronautics and Space Administration.

[FR Doc. 2012–5525 Filed 3–6–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 4, 25, and 52

[FAC 2005–57; FAR Case 2012–004; Docket 2012–0004, Sequence 1]

RIN 9000–AM18

Federal Acquisition Regulation; United States-Korea Free Trade Agreement

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule.

SUMMARY: DoD, GSA, and NASA are issuing an interim rule amending the Federal Acquisition Regulation (FAR) to implement the United States-Korea Free Trade Agreement. The Republic of Korea is already party to the World Trade Organization Government Procurement Agreement, but this trade agreement implements a lower procurement threshold.

DATES: *Effective Date:* March 15, 2012.

Comment Date: Interested parties should submit written comments to the Regulatory Secretariat on or before May 7, 2012 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments identified by FAC 2005–57, FAR Case 2012–004, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov*. Submit comments via the Federal eRulemaking portal by inputting ''FAR Case 2012–004'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''FAR Case 2012–004.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''FAR Case 2012–004'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Hada Flowers, 1275 First Street NE., 7th Floor, Washington, DC 20417.

Instructions: Please submit comments only and cite FAC 2005–57, FAR Case 2012–004, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah Erwin, Attorney-Advisor in the Office of Governmentwide Policy, at 202–501–2164 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAC 2005–57, FAR Case 2012–004.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule amends FAR part 25 and the corresponding provisions and clauses in part 52 to implement the United States-Korea Free Trade Agreement (see the United States-Korea Free Trade Agreement Implementation Act (Pub. L. 112–41) (19 U.S.C. 3805 note)).

The Republic of Korea is already party to the World Trade Organization Government Procurement Agreement (WTO GPA). This Free Trade Agreement (FTA) now covers acquisition of supplies and services between $100,000 and the current WTO GPA threshold of $202,000, lowering the threshold for—

• Waiver of the applicability of the Buy American statute (41 U.S.C. chapter 83) for some foreign supplies and construction materials from the Republic of Korea; and

• Applicability of specified procurement procedures designed to ensure fairness in the acquisition of supplies and services (see FAR 25.408). These obligations include, among others, that an agency shall not impose the condition that, in order for an offeror to be allowed to submit an offer or be awarded a contract, the offeror has been previously awarded one or more contracts by an agency of the United States Government or that the offeror has prior work experience in the United States (see FAR 15.305(a)(2)(iv)).

II. Discussion and Analysis

This interim rule adds the Republic of Korea to the definition of ''Free Trade Agreement country'' in multiple locations in the FAR. The Republic of Korea was already listed as a designated country because it is party to the WTO GPA. The excluded services for Korea FTA are the same as for the WTO GPA.

By implementation of this Korea FTA, eligible goods and services from Korea are now covered when valued at or above $100,000, rather than at or above the WTO GPA threshold of $202,000. The threshold for the Korea FTA for construction is the same as the threshold for the WTO GPA for construction.

The Korea FTA $100,000 threshold for supplies and services is higher than the threshold for supplies and services for most of the FTAs ($77,494), but not as high as the Bahrain, Morocco, Oman, and Peru FTA threshold for supplies and services ($202,000). Therefore, new alternates are required for the Buy American Act—Free Trade Agreements—Israeli Trade Act provision and clause (FAR 52.225–3 and 52.225–4) to cover acquisitions that are valued at $77,494 or more but less than $100,000. In that dollar range, all FTAs are applicable except for the Bahrain, Korea, Morocco, Oman, and Peru FTAs.

Because the Korea FTA construction threshold of $7,777,000 is the same as the WTO GPA threshold, no new clause alternates are required for the Buy American Act—Construction Materials under Trade Agreements provision and clause (FAR 52.225–11 and 52.225–12) or the Recovery Act clauses at FAR 52.225–23 and 52.225–24.

Some minor editorial type corrections are also included in this rule to—

• Include the public law number and 19 U.S.C. reference for all Free Trade Agreements;

• Correct references to 41 U.S.C. chapter 83 and 41 U.S.C. 1907 (based on the recent positive law codification of title 41);

• Delete an unnecessary definition of ''Canadian end product'' in FAR 25.003 (term is only used in the provisions and clauses, and is defined at FAR 52.225–3 Buy American Act—Free Trade Agreements—Israeli Trade Act); and

• Provide consistency in paragraph (c) of FAR 52.225–3 between basic clause and alternates, except to the extent that a change is required due to the applicability of trade agreements. This consists of adding to Alternates I and II the statement that the Buy American Act provides a preference for domestic goods, and that the component test of the Buy American Act has been waived for end products that are commercially available off-the-shelf items, in accordance with 41 U.S.C. 1907.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Korea is already a designated country under the WTO GPA. Although the rule now opens up Government procurement to the goods and services of Korea at or above the threshold of $100,000, DoD, GSA, and NASA do not anticipate any significant economic impact on U.S. small businesses. The Department of Defense only applies the trade agreements to the non-defense items listed at Defense Federal Acquisition Regulation Supplement 225.401–70, and acquisitions that are set aside or provide other form of preference for small businesses are exempt. FAR 19.502–2 states that acquisitions of supplies or services with an anticipated dollar value between $3,000 and $150,000 (with some exceptions) are automatically reserved for small business concerns. Therefore, DoD, GSA, and NASA have not performed an Initial Regulatory Flexibility Analysis.

DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (FAR Case 2012–004), in correspondence.

V. Paperwork Reduction Act

This rule affects the certification and information collection requirements in the provisions at FAR 52.212–3, 52.225–4, 52.225–6, and 52.225–11 currently approved under OMB clearances 9000–0136, 9000–0130, 9000–0025, and 9000–0141 respectively, in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible, because it is just a question of which category offered goods from the Republic of Korea would be listed under.

VI. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense (DoD), the Administrator of General Services (GSA), and the Administrator of the National Aeronautics and Space Administration (NASA) that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. This action is necessary because the Free Trade Agreement with the Republic of Korea takes effect on March 15, 2012. This is a reciprocal agreement, approved by Congress and the President of the United States. It is important for the United States Government to honor its new trade obligations to the Republic of Korea, as the Republic of Korea in turn honors its new trade obligations to the United States. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD, GSA, and NASA will consider public

comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 4, 25, and 52

Government procurement.

Dated: March 1, 2012.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 4, 25, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 4, 25, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 4—ADMINISTRATIVE MATTERS

■ 2. Amend section 4.1202 by revising paragraph (v) to read as follows:

4.1202 Solicitation provision and contract clause.

* * * * *

(v) 52.225–4, Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate (Basic, Alternates I, II, and III).

* * * * *

PART 25—FOREIGN ACQUISITION

25.003 [Amended]

■ 3. Amend section 25.003 by—

■ a. Removing the definition ''Canadian end product'';

■ b. In paragraph (2) of the definition ''Designated country'' removing ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place; and

■ c. In the definition ''Free Trade Agreement country'' removing ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place.

■ 4. Amend section 25.400 by—

■ a. Removing from paragraph (a)(2)(i) ''Act of 1993'' and adding ''Act of 1993 (Pub. L. 103–182)'' in its place;

■ b. Removing from paragraph (a)(2)(ii) ''Act (Pub. L. 108–77'' and adding ''Act (Pub. L. 108–77) (19 U.S.C. 3805 note)'' in its place;

■ c. Removing from paragraph (a)(2)(viii) ''and'';

■ d. Removing from paragraph (a)(2)(ix) '';'' and adding ''; and'' in its place; and

■ e. Adding paragraph (a)(2)(x).

The added text reads as follows:

25.400 Scope of subpart.

(a) * * *

(2) * * *

(x) Korea FTA (the United States-Korea Free Trade Agreement Implementation Act (Pub. L. 112–41) (19 U.S.C. 3805 note));

* * * * *

25.401 [Amended]

■ 5. Amend section 25.401 in the table that follows paragraph (b) by removing from the table heading ''WTO GPA'' and adding ''WTO GPA AND KOREA FTA'' in its place; and by removing from paragraph (6) ''–V503''.

■ 6. Amend section 25.402 by revising the table that follows paragraph (b) to read as follows:

25.402 General.

* * * * *

(b) * * *

Trade agreement	Supply contract (equal to or exceeding)	Service contract (equal to or exceeding)	Construction contract (equal to or exceeding)
WTO GPA	$202,000	$202,000	$7,777,000
FTAs:			
Australia FTA	77,494	77,494	7,777,000
Bahrain FTA	202,000	202,000	10,074,262
CAFTA–DR (Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua)	77,494	77,494	7,777,000
Chile FTA	77,494	77,494	7,777,000
Korea FTA	100,000	100,000	7,777,000
Morocco FTA	202,000	202,000	7,777,000
NAFTA:	.....	.....	.....
—Canada	25,000	77,494	10,074,262
—Mexico	77,494	77,494	10,074,262
Oman FTA	202,000	202,000	10,074,262
Peru FTA	202,000	202,000	7,777,000
Singapore FTA	77,494	77,494	7,777,000
Israeli Trade Act	50,000	.....	.....

■ 7. Amend section 25.1101 by adding paragraphs (b)(1)(iv) and (b)(2)(iv) to read as follows:

25.1101 Acquisition of supplies.

* * * * *

(b)(1) * * *

(iv) If the acquisition value is $77,494 or more but is less than $100,000, use the clause with its Alternate III.

(2) * * *

(iv) If the acquisition value is $77,494 or more, but is less than $100,000, use the provision with its Alternate III.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 8. Amend section 52.204–8 by revising the date of the provision and the introductory text of paragraph (c)(1)(xvii); and adding paragraph (c)(1)(xvii)(D).

The revised and added text reads as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

ANNUAL REPRESENTATIONS AND CERTIFICATIONS (MAR 2012)

* * * * *

(c)(1) * * *

(xvii) 52.225–4, Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225–3.

* * * * *

(D) If the acquisition value is $77,494 or more but is less than $100,000, the provision with its Alternate III applies.

* * * * *

■ 9. Amend section 52.212–3 by—

■ a. Revising the date of the provision;
■ b. Redesignating paragraph (g)(4) as paragraph (g)(5);
■ c. Adding a new paragraph (g)(4); and
■ d. Removing from the newly redesignated paragraph (g)(5)(i) ''paragraph (g)(4)(ii)'' and adding ''paragraph (g)(5)(ii)'' in its place.

The revised and added text reads as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

OFFEROR REPRESENTATIONS AND CERTIFICATIONS—COMMERCIAL ITEMS (MAR 2012)

* * * * *

(g) * * *

(4) *Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate, Alternate III.* If Alternate III to the clause at 52.225–3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled ''Buy American Act—Free Trade Agreements—Israeli Trade Act'':

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, or Peruvian End Products) or Israeli End Products:

LINE ITEM NO.	COUNTRY OF ORIGIN

[*List as necessary*]

* * * * *

■ 10. Amend section 52.212–5 by revising the date of the clause, and paragraphs (b)(40) and (b)(41) to read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *

CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (MAR 2012)

* * * * *

(b) * * *

__(40)(i) 52.225–3, Buy American Act—Free Trade Agreements—Israeli Trade Act (Mar 2012) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103–182, Pub. L. 108–77, 108–78, 108–286, 108–302, 109–53, 109–169, 109–283, 110–138, and Pub. L. 112–41).

__(ii) Alternate I (Mar 2012) of 52.225–3.

__(iii) Alternate II (Mar 2012) of 52.225–3.

__(iv) Alternate III (Mar 2012) of 52.225–3.

__(41) 52.225–5, Trade Agreements (Mar 2012) (19 U.S.C. 2501, *et seq.,* 19 U.S.C. 3301 note).

* * * * *

■ 11. Amend section 52.225–3 by—
■ a. Revising the date of the provision;
■ b. In paragraph (a) in the definition ''Free Trade Agreement country'' removing ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place;
■ c. Removing from the first sentence of paragraph (c) ''(41 U.S.C. 10a–10d)'' and adding ''(41 U.S.C. chapter 83)'' in its place;
■ d. Removing from the second sentence of paragraph (c) ''41 U.S.C. 431'' and adding ''41 U.S.C. 1907'' in its place;
■ e. Removing from the introductory text of Alternate I ''(JAN 2004)'' and adding ''(MAR 2012)'' in its place;
■ f. Removing from the first sentence in paragraph (c) of Alternate I ''The Contracting Officer'' and adding ''41 U.S.C. chapter 83 provides a preference for domestic end products for supplies acquired for use in the United States. In accordance with 41 U.S.C. 1907, the component test of the Buy American Act is waived for an end product that is a COTS item (See 12.505(a)(1)). In addition, the Contracting Officer'' in its place;
■ g. Removing from the introductory text of Alternate II ''(JAN 2004)'' and adding ''(MAR 2012)'' in its place;
■ h. Removing from the first sentence in paragraph (c) of Alternate II ''The Contracting Officer'' and adding ''41 U.S.C. chapter 83 provides a preference for domestic end products for supplies acquired for use in the United States. In accordance with 41 U.S.C. 1907, the component test of the Buy American Act is waived for an end product that is a COTS item (See 12.505(a)(1)). In addition, the Contracting Officer'' in its place; and
■ i. Adding Alternate III.

The revised and added text reads as follows:

52.225–3 Buy American Act—Free Trade Agreements—Israeli Trade Act.

* * * * *

BUY AMERICAN ACT—FREE TRADE AGREEMENTS—ISRAELI TRADE ACT (MAR 2012)

* * * * *

Alternate III (MAR 2012). As prescribed in 25.1101(b)(1)(iv), delete the definition of ''Bahrainian, Moroccan, Omani, or Peruvian end product'' and add in its place the following definition of ''Bahrainian, Korean, Moroccan, Omani, or Peruvian end product'' in paragraph (a) of the basic clause; and substitute the following paragraph (c) for paragraph (c) of the basic clause:

Bahrainian, Korean, Moroccan, Omani, or Peruvian end product means an article that—

(1) Is wholly the growth, product, or manufacture of Bahrain, Korea (Republic of), Morocco, Oman, or Peru; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Bahrain, Korea (Republic of), Morocco, Oman, or Peru into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

(c) *Delivery of end products.* 41 U.S.C. chapter 83 provides a preference for domestic end products for supplies acquired for use in the United States. In accordance with 41 U.S.C. 1907, the component test of the Buy American Act is waived for an end product that is a COTS item (See 12.505(a)(1)). In addition, the Contracting Officer has determined that FTAs (except the Bahrain, Korea (Republic of), Morocco, Oman, and Peru FTAs) and the Israeli Trade Act apply to this acquisition. Unless otherwise specified, these trade agreements apply to all items in the Schedule. The Contractor shall deliver under this contract only domestic end products except to the extent that, in its offer, it specified delivery of foreign end products in the provision entitled ''Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate.'' If the Contractor specified in its offer that the Contractor would supply a Free Trade Agreement country end product (other than a Bahrainian, Korean, Moroccan, Omani, or Peruvian end product) or an Israeli end product, then the Contractor shall supply a Free

Trade Agreement country end product (other than a Bahrainian, Korean, Moroccan, Omani, or Peruvian end product), an Israeli end product or, at the Contractor's option, a domestic end product.

■ 12. Amend section 52.225–4 by adding Alternate III to read as follows:

52.225–4 Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate.

* * * * *

Alternate III (MAR 2012). As prescribed in 25.1101(b)(2)(iv), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled ''Buy American Act—Free Trade Agreements—Israeli Trade Act'':

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, or Peruvian End Products) or Israeli End Products:

LINE ITEM NO.	COUNTRY OF ORIGIN

[*List as necessary*]

■ 13. Amend section 52.225–5 by—

■ a. Revising the date of the clause; and

■ b. In paragraph (a) in the definition ''Designated country'' removing from paragraph (2) ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place.

The revised text reads as follows:

52.225–5 Trade Agreements.

* * * * *

TRADE AGREEMENTS (MAR 2012)

* * * * *

■ 14. Amend section 52.225–11 by—

■ a. Revising the date of the clause;

■ b. In paragraph (a) in the definition ''Designated country'' removing from paragraph (2) ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place;

■ c. Removing from the first sentence of paragraph (b)(1) ''(41 U.S.C. 10a–10d)'' and adding ''(41 U.S.C. chapter 83)'' in its place;

■ d. Removing from the second sentence of paragraph (b)(1) ''41 U.S.C. 431'' and adding ''41 U.S.C. 1907'' in its place;

■ e. Removing from the introductory text of Alternate I ''(JUN 2009)'' and adding ''(MAR 2012)'' in its place;

■ f. Removing from the first sentence in paragraph (b)(1) of Alternate I ''(41 U.S.C. 10a–10d)'' and adding ''(41 U.S.C. chapter 83)'' in its place; and

■ g. Removing from the second sentence in paragraph (b)(1) of Alternate I ''41 U.S.C. 431'' and adding ''41 U.S.C. 1907'' in its place.

The revised text reads as follows:

52.225–11 Buy American Act—Construction Materials Under Trade Agreements.

* * * * *

BUY AMERICAN ACT—CONSTRUCTION MATERIALS UNDER TRADE AGREEMENTS (MAR 2012)

* * * * *

■ 15. Amend section 52.225–23 by—

■ a. Revising the date of the clause;

■ b. In paragraph (a) in the definition ''Designated country'' removing from paragraph (2) ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place; and

■ c. In paragraph (a) in the definition ''Recovery Act designated country'' removing from paragraph (2) ''Honduras, Mexico'' and adding ''Honduras, Korea (Republic of), Mexico'' in its place.

The revised text reads as follows:

52.225–23 Required Use of American Iron, Steel, and Manufactured Goods—Buy American Act—Construction Materials under Trade Agreements.

* * * * *

REQUIRED USE OF AMERICAN IRON, STEEL, AND MANUFACTURED GOODS—BUY AMERICAN ACT—CONSTRUCTION MATERIALS UNDER TRADE AGREEMENTS (MAR 2012)

* * * * *

[FR Doc. 2012–5528 Filed 3–6–12; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket FAR 2012–0081, Sequence 2]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–57; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DOD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rule appearing in Federal Acquisition Circular (FAC) 2005–57, which amends the Federal Acquisition Regulation (FAR). Interested parties may obtain further information regarding this rule by referring to FAC 2005–57, which precedes this document. These documents are also available via the Internet at *http://www.regulations.gov*.

DATES: March 7, 2012.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below. Please cite FAC 2005–57 and the FAR case number. For information pertaining to status or publication schedule, contact the Regulatory Secretariat at 202–501–4755.

LIST OF RULE IN FAC 2005–57

Subject	FAR case	Analyst
United States-Korea Free Trade Agreement (Interim)	2012–004	Erwin

SUPPLEMENTARY INFORMATION: A Summary for the FAR rule follows. For the actual revisions and/or amendments made by this FAR case, refer to FAR Case 2012–004.

FAC 2005–57 amends the FAR as specified below:

United States-Korea Free Trade Agreement (FAR Case 2012–004) (Interim)

This interim rule implements the United States-Korea Free Trade Agreement (see the United States-Korea Free Trade Agreement Implementation Act (Pub. L. 112–41) (19 U.S.C. 3805 note)).

The Republic of Korea is already party to the World Trade Organization Government Procurement Agreement (WTO GPA). This Free Trade Agreement now covers acquisition of supplies and services between $100,000 and the current WTO GPA threshold of $202,000. This interim rule is not expected to have a significant economic impact on a substantial number of small entities.

Dated: March 1, 2012.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–5530 Filed 3–6–12; 8:45 am]

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